

Methods of breastmilk expression: An evidence review to inform guidelines and research priorities

A thesis submitted by

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Abstract

Background

Knowing which methods of breastmilk expression are effective and acceptable is important to inform clinical guidelines and enable breastfeeding of infants, particularly premature, sick and low birth weight infants.

Objectives

To evaluate the best available evidence on effects and acceptability of methods of breastmilk expression and inform guidelines and research priorities.

Methods

Systematic review using Cochrane methods. Electronic databases (PubMed, CINAHL, Embase, Scopus, Cochrane Central) and references of included studies were searched (July 2018). Selection criteria were RCTs comparing breastmilk expression interventions against standard care or each other, in women who had given birth to premature or term infants. Primary outcomes were quantity of milk expressed, quality of milk expressed and maternal satisfaction. Risk of bias of included studies was assessed.

Main results

One Cochrane systematic review (including 41 trials) and 10 additional RCTs were included. A total of 10,134 women and their infants, most premature, were randomised in the 51 included trials, performed in a range of high-, middle-, and low-income countries. 42 RCTs contributed outcomes (data or narrative) to the review synthesis, which reported 19 comparisons. Five comparisons evaluated pump versus hand expression, seven assessed different types of pumps/pumping, four evaluated instruction/education and support, and three pumping techniques or protocols relating to timing of expression (n=3). In most trials contributing data fewer participants than the number randomised were included in the analysis, with a maximum of 1533 women included. Overall risk of bias was unclear due to lack of methodological details reported. Lack of data prohibited GRADE, subgroup and sensitivity analyses.

For **quantity of milk expressed**, there was evidence of higher mean volume in the manual pump group compared with the hand expression group. Considering **quality of milk expressed**: sodium and protein concentration measures indicated a lower milk quality for women who expressed using any manual pump compared with hand expression; and sodium concentrations were lower quality for women who expressed using a large electric pump compared to hand expression. There was a higher fat content in women who expressed using any method plus breast massage compared with no breast massage. Regarding **maternal satisfaction**, women who used the large electric pump compared with hand expression were less satisfied (when satisfaction was compared with instruction). Women using higher vacuum pressures with their electric pump reported a higher level of confidence at discharge and at one-month post discharge.

Conclusion

The evidence for effective methods of expressing is not yet clear. Further RCTs are required to inform guidelines. The full range of interventions health practitioners suggest may have positive effects on quantity and quality of milk expressed should be evaluated in future trials, which should assess a standard set of clinical outcomes, cost and maternal satisfaction, using similar measures, and at similar timepoints. Future trial should assess if/how effects vary by characteristics of mother-infant dyads, including gestational age at birth, singleton versus multiples, time since birth, mode of birth, and health status of mothers.

Summary of the review

Background

Breastfeeding is important for all infants, particularly when they are premature, low weight or sick. However, not all infants can feed at the breast. Mothers may also want to express milk for their own comfort or to increase supply, including for donating to human milk banks. Knowing which interventions enable effective and acceptable methods of breastmilk expression is important.

Objectives

Primary: to assess the effects and acceptability of methods of breastmilk expression for lactating women.

Secondary: to inform research and best practice guidelines relating to breastmilk expression for lactating women.

Methods

We used Cochrane methods for systematic review.

Search: We searched electronic databases including PubMed, CINAHL, Embase, Scopus, Cochrane Central (July 2018), and reference lists of retrieved studies.

Selection criteria: Participants were preterm infants in neonatal units or healthy infants at home, and their mothers. Systematic reviews and randomised controlled trials (RCTs) comparing breastmilk expression interventions with standard care, or one breastmilk expression method compared with another, were eligible. All types of breastmilk expression interventions were eligible including: 1) pumping equipment and method (e.g. pump, hand expression); 2) protocols relating to timing of expression (initiation, frequency, duration) and/or technique (e.g. pressure); and 3) education or other support (e.g. relaxation, warming the breast). Primary outcomes were quantity of milk expressed, quality of milk expressed (e.g. nutrients) and maternal satisfaction. Secondary outcomes included (but were not limited to) breastfeeding, transfer to feeding at the breast, maternal anxiety, adverse effects (e.g. contamination of expressed breastmilk, cessation of pumping or expressing due to difficulties with pumping or expressing) and cost of pumping equipment.

Data extraction and analysis: Two review authors independently assessed trial eligibility, extracted data, and assessed the risk of bias in the included studies. We used RevMan 2014 for the statistical analysis. Due to one study only being included in each analysis (except for the analysis for one outcome, which included two studies), we performed fixed effect meta-analysis for all comparisons and outcomes.

Main results

Overall, 10,134 mothers and their infants were involved in the 51 studies included in our review, with 42 of the included trials (9596 women and infants randomised) contributing data or narrative outcomes. We identified one Cochrane systematic review (Becker 2016) including 41 trials (last search date 21 March 2016) and another 10 RCTs not included in the Becker review for inclusion, which we combined in a new synthesis, evaluated and interpreted. 9596 women and infants were randomised in the 42 trials that contributed to the

synthesis. For the majority of trials that contributed data to the review analyses, far fewer women were included in the analyses than were randomised, with a maximum of 1533 women included. Due to diversity across the included trials in the nature of the interventions assessed, and in outcome measures used, many comparisons were assessed in separate analyses, with only one study included in all except one analysis. Overall, data were included in analysis for 15 comparisons (13 reporting one of the primary outcomes), and narrative outcomes were reported for four additional comparisons. The nineteen comparisons were categorised as: pump versus hand (five, analysis 1-5); type of pump/pumping (seven, analysis 6-12); instruction/education and other support (four, analysis 13-16) and protocols relating to technique or timing of expression (three, analysis 17-19). Data in a format suitable for analysis were reported for quantity of milk expressed by 19 trials, quality of milk expressed by six trials, and maternal satisfaction by three trials. Many risk of bias items judged were unclear due to lack of methodological details reported, most included trials were at risk of performance bias, and there was attrition bias in some trials. The included trials were performed in a mix of high-, middle-, and low-income countries. We were unable to perform planned GRADE analysis, subgroup analyses or sensitivity analyses, due to lack of data and variation across trials in outcome measures.

Considering the primary outcome **quantity of milk expressed**, and the *pump/hand comparisons*. There was evidence of higher mean volume over six days pumping in the manual pump group compared with the hand expression group (MD 212.10 mls, 95% CI 9.39 to 414.81; 48 participants; 1 trial), however no evidence of a difference between these groups in volume of milk expressed on day 4-5 (MD 73.94 mls, 95% CI -64.11 to 211.99; 28 participants; 1 trial). We observed a higher mean volume over six days pumping in the large electric pump group compared with hand expression group (MD 373.10 mls, 95% CI 161.09 to 585.11, 43 participants; 1 trial), and a higher mean volume/day assessed on day 2 (MD 15.65 mls, 95% CI 0.95 to 30.35; 26 participants; 1 trial), 3 (MD 51.11 mls, 95% CI 5.12 to 97.10; 26 participants; 1 trial), 4 (MD 100.5 mls, 95% CI 18.33 to 182.67; 26 participants; 1 trial) and 5 (MD 128 mls, 95% CI 30.64 to 225.87; 51 participant; 2 trials) in the large electric pump compared with the hand expression group. However, there was no evidence of a difference between the large electric pump and hand expression group in volume from 1 expression (MD 2.10 mls, 95% CI -0.57 to 4.77; 68 participants; 1 trial), volume/day assessed on day 6 (MD 124.87 mls, 95% CI -22.09 to 271.8; 26 participants; 1 trial) or 7 (MD 124.9 mls, 95% CI -53.37 to 303.17; 26 participants; 1 trial). We observed no difference between the hand expression for 7 days versus 3 days prior to electric pump use groups in mean volume/day assessed on day 14 (MD 117.30 mls, 95% CI -192.60 to 427.20; 34 participants; 1 trial). There was a higher mean quantity of milk in women who expressed using any method with breast massage compared with no breast massage (MD 4.82 ml, 95% CI 1.25 to 8.39; 72 participants; 1 trial).

Regarding the *pump/pumping comparisons*, for manual pump versus another manual pump a higher mean quantity of milk expressed over 24 hours was observed for women in the Isis pump group compared with the Evenflo pump group (MD 30.49 ml, 95% CI 3.40 to 57.58; 32 participants; 1 trial) and for women in the Harmony pump group compared with the Evenflo group (MD 28.50 ml, 95% CI 12.11 to 44.89; 32 participants; 1 trial); however no difference in this quantity of milk measures for women in the Isis compared with Harmony pump (MD 4.57 ml, 95% CI 13.42 to 22.56; 32 participants; 1 trial), Isis versus Little Heart pump (MD 15.02 ml, 95% CI -13.32 to 42.36; 32 participants; 1 trial) Harmony versus Little Heart pump (MD 12.13 ml, 95% CI -9.68 to 33.94; 32 participants; 1 trial) or Little Heart versus Evenflo pump (MD 15.47 ml, 95% CI -75.3 to 106.2; 32 participants; 1 trial) groups. There was no difference between women using any type of battery versus a small electric pump in mean volume of milk over one expression (MD 15 ml, 95% CI -8.33 to 38.33; 40 participants; 1 trial). No difference was observed between women using a large electric versus manual pump

in mean volume over 6 days pumping (MD 161 ml, 95% CI -66 to 388.90; 53 participants; 1 trial), mean volume per day (MD 5.07, 95% CI -56.59 to 66.73; 145 participants; 1 trial) or mean volume expressed on day 5 (MD 150.68 mls, 95% CI -138.02 to 439.38; 27 participants; 1 trial). There was no difference between simultaneous compared with sequential pumping in mean total quantity of milk expressed over weeks 2-5 (MD 4298.94 g, 95% CI -1056.80 to 9654.68; 49 participants; 1 trial). We observed a higher mean volume of milk expressed over one expression in the large electric pump compared with battery/small electric pump group (MD 20.00 ml, 95% CI 1.28 to 38.72; 40 participants; 1 trial), however no difference between these groups in two other quantity of milk measures. For the remaining two pump/pumping comparisons no trial provided any data on quantity of milk expressed.

Considering the *instruction/education and support comparisons*, we observed a higher mean quantity assessed as volume on day 14 (MD 503.40 mls, 95% CI 410.76 to 595.84, 160 participants; 1 trial) with a relaxation technique compared with no relaxation technique, and the same trial showed a difference in this quantity of milk measure assessed on day 1, 5 and 10. However, another trial showed no evidence of a difference in women who expressed with and without a relaxation in change in volume/day, assessed on day seven (MD 2.24 cc, 95% CI -1.78 to 6.26; participants; 56 participants; 1 trial). We observed a higher mean change in volume of breastmilk assessed on day 7 (MD 7.60 ml, 95% CI 4.45 to 10.75; 74 participants; 1 trial) and change in volume/day assessed on day 7 (MD 58.0 ml, 95% CI 23.19 to 75.01; 74 participants; 1 trial) in women who expressed following foot massage and reflexology focused on milk production points compared to women who expressed following general foot massage. There was no clear difference observed between the group of women who received instruction support versus no specific instruction support in six quantity of milk measures. We observed a higher mean quantity of milk expressed during one expression in women who warmed the breast compared with no warming for most of the expression sessions assessed (4/6).

Considering the *pumping technique or timing*, comparisons, the mean milk output over 8-hours (8:00 am to 4:00 pm) on day 4 after birth was higher in women who pumped using a high vacuum pressure (-150mmHg) compared with lower vacuum pressure (-100 mmHg) (MD 61.68 g, 95% CI 39.28 to 84.08; 98 participants; 1 trial). No data on quantity of milk expressed was provided for timing of initiation of breastmilk expression or frequency of breast expression.

In relation to **quality of milk expressed** (nutrients), the sodium concentration (MD -6.00 mmol/L, 95% CI -9.79 to -2.21; 118 participants; 1 trial) and protein concentration (MD -1.30 g/L, 95% CI -2.56 to -0.04; 118 participants; 1 trial) measures signalled a lower milk quality for women who expressed using a manual pump compared with hand expression. However, no difference was observed between women who expressed using a manual pump compared with hand expression in potassium concentration (MD 1.20 mmol/L, 95% CI 0.04 to 2.36; 118 participants; 1 trial), or in energy content (MD 28.20 kcal/L, 95% CI -16.94 to 75.54; 141 participants; 1 trial). The sodium concentration measure (MD -6.90 mmol/L, 95% CI -10.58 to -3.22; 111 participants; 1 trial) indicated a lower quality of milk expressed by women who used a large electric pump compared with hand expression, however we observed no difference between these groups in a range of other quality of milk measures. There was a higher fat content (Creatocrit %) in women who expressed using any method plus breast massage compared with no breast massage (MD 1.92 %, 95% CI 1.02 to 2.82; 72 participants; 1 trial), indicating that breast massage may improve quality of milk expressed. We observed a higher protein content in the milk of women who expressed using a large electric pump compared with manual pump (MD 1.40 g/L (0.08 to 2.72; 121 participants; 1 trial), suggesting a higher quality with the large electric pump. However, no difference was observed between these groups of women in sodium and potassium concentration, or in

protein content of milk expressed. There was a higher fat content in milk expressed on day 1 (MD 8.60 g/L/day, 95% CI 3.66 to 13.54; 160 participants; 1 trial), day 5 (MD 12.00 g/L/day, 95% CI 5.17 to 18.83; 160 participants; 1 trial), day 10 (MD 14.00 g/L/day, 95% CI 2.25 to 25.75; 160 participants; 1 trial) and day 14 (MD 21.70 g/L/day, 95% CI 17.87 to 25.53; 160 participants; 1 trial) in women who expressed with a relaxation technique compared with no relaxation, indicating relaxation may improve quality of milk expressed. No data on quality of milk expressed were provided by the included trials for any of the other comparisons reported.

Regarding **maternal satisfaction**, three studies provided data suitable for analysis, assessing different measures. One study assessed satisfaction with instructions provided using the breast milk expression experience (BMEE) scale (items scored on 1-5 scale, from 1 strongly disagree to 5 strongly agree, higher score is better), and women who used the large electric pump compared with hand expression were less satisfied (MD -0.40, 95% CI -0.75 to -0.05; 68 participants). A study assessing maternal lactation (confidence) using the Chinese version of the H&H scale (20-item self-evaluated tool, higher scores represent greater satisfaction in lactation) showed a higher level of confidence at discharge (MD 5.09, 95% CI 0.01 to 10.17; 98 participants) and one month following discharge (MD 13.55, 95% CI 3.52 to 23.58; 98 participants), in mothers who expressed using a high-pressure vacuum protocol compared with a lower pressure vacuum protocol. We observed no evidence of a difference in maternal satisfaction (self-efficacy) assessed using the Breastfeeding Self-Efficacy Scale (score), between mothers who practice hand expression for seven versus for three days prior following delivery prior to expressing with an electric pump (MD -3.80, 95% CI -12.19 to 4.59; 34 participants; 1 trial).

Authors' conclusions

Due to multiple interventions and comparisons, and few participants providing outcomes data, the evidence for effective methods of expressing is not yet clear.

Future well designed studies are needed in this area to inform guidelines and best practice. To build an adequate evidence base to inform best practice breastmilk expression, it is important that future studies use similar measures of outcomes (including the primary review outcomes), assess participants at common key time points, and consider if/how intervention effects are modified by participant characteristics (e.g. gestational age at birth, time since birth, singletons versus multiples). Studies assessing overall breastfeeding support interventions and including breastmilk expression components should clearly identify the breastmilk expression intervention(s) assessed, and report results for each separately.

Declaration

I certify that this work contains no material which has been accepted for the award of any other degree or diploma in my name, in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission in my name, for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint award of this degree.

I acknowledge the support I have received for my research through the provision of an Australian Government Research Training Program Scholarship.

I give permission for the digital version of my thesis to be made available on the web, via the University's digital research repository, the Library Search and also through web search engines, unless permission has been granted by the University to restrict access for a period of time.

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Abbreviations

BFHI	Baby Friendly Hospital Initiative
BMEE	Breastmilk expression experience
BPSP	Breast pump suction pattern
BSES-SF	Breastfeeding Self-Efficacy scale – short form
CI	Confidence interval
DASS	Depression anxiety stress scale
EPDS	Edinburgh Postnatal Depression Scale
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GriP	Getting research into practice
HIV	Human Immune deficiency Virus
JBIPACES	Joanna Briggs Institute Practical Application of Clinical Evidence System
LGA	Local government area
MCHN	Maternal child health nurse
MD	Mean difference
NHMRC	National Health and Medical Research Council
NEC	Necrotising enterocolitis
NICU	Neonatal intensive care unit
RCT	Randomised controlled trial
ROB	Risk of bias
RR	Risk ratio
SILC-MCHN	Supporting breastfeeding in local communities’ maternal child health nurse
SD	Standard deviation
SFR	Single family room
SoF	Summary of findings
SMS	Short message service
UNICEF	United Nations International Children’s Fund
VLBW	Very low birth weight
WHO	World Health Organization

Chapter 1: Background and objective

1.16 Description of the condition

The importance of breastfeeding and human milk

Breastfeeding is a dynamic, interactive process. Breast stimulation, preferably by the infant, is needed shortly after birth to establish and maintain breast milk supply in women. Once an infant is correctly attached to the breast (tongue cupping under the areola with the nipple at the junction of the hard and soft palate), a combination of negative pressure, as the infant's jaw lowers, and positive pressure (oxytocin release in response to infant sucking) draws breast milk into the infant's mouth (McNeilly 1983; Weitzman 1980). As the suck cycle progresses, the infant's tongue rises, with continued negative pressure to the roof of the mouth, clearing milk toward the pharynx to be swallowed (Cannon 2016; Woolridge 1986).

The value of breastfeeding and breastmilk for health of mothers and young infants is widely acknowledged (Ip 2009). Breastmilk protects against diarrhoea, respiratory infection, otitis media among children, **mortality** associated with necrotizing enterocolitis (NEC), and sudden infant death syndrome (Ip 2009; Victoria 2016). Protective effects of breastfeeding practices on breast and ovarian cancer have also been documented in breastfeeding mothers (Victoria 2016). The World Health Organization (WHO) recommends that infants should be fed exclusively on human milk from birth to six months, and that human milk feeds feeding should be continued thereafter with appropriate complementary foods (WHO 2017).

Breastmilk is important for all infants, but particularly vulnerable infants, including preterm, low-weight and clinically unstable infants. Studies have indicated that preterm infants fed with formula are at an increased risk of morbidity associated with prematurity, including feeding intolerance, retinopathy, late onset of sepsis and (NEC) compared with those fed breastmilk (Ip 2009; Lewis 2017). Necrotizing enterocolitis (NEC) is one of the most significant causes of morbidity and mortality among premature infants. Studies have also indicated that breast milk is important to support optimal brain development and developmental outcomes in preterm infants (Bharwani 2016; Lechner 2017).

Despite the benefits of breastfeeding, recent studies suggest that only 37% of mothers follow international recommendation of exclusive breastfeeding (Victoria 2016) or achieve their intended breastfeeding goals (Galipeau 2017). The first four to six weeks after birth have been identified as a critical period for cessation of breastfeeding or its exclusivity, with maternal milk supply concern frequently reported for stopping breastfeeding earlier than intended (Galipeau 2017).

Breastmilk expression and its importance

Breast milk expression is the mechanical removal of milk from the breast, or massage of the breast, by which breast milk is physically released from the breast through compression. This is under the assumption that hormones are at sufficient levels and the breast has developed adequate glandular tissue for milk production, or galactopoiesis to occur (Eglash 2015; Wambach 2015). The hormone prolactin plays an important role in promotion of breast milk production. Within seconds of stimulation, levels can increase anywhere from 80 to 150% of baseline. Maintenance of breast milk production relies on periodic surges of prolactin along with adequate breast storage capacity that is being continually refilled (Eglash 2015). If the

breast is not being adequately stimulated by the infant, then breast expression is necessary for this process to keep occurring (Wambach 2015).

Hand expression or massage creates a positive form of pressure through this compression which builds on the pressure already manifested in the milk ducts during let-down (when the hormone oxytocin exerts internal pressure on the milk ducts within the breast releasing breastmilk into the ducts) (Eglash 2015). Oxytocin facilitates milk removal. Whilst oxytocin can be mechanically triggered by hand expressing, manual or electric pump, a 'let-down' reflex can be also influenced by external stimuli such as a mother's baby crying, a mother looking at her baby's photo or even a mother smelling her baby. The use of a breast pump (either manual or electric) most often involves the presence of vacuum within the apparatus when activated (generating increased internal pressure as described above). An electric pump uses the action of vacuum allowing the woman to adjust cycling patterns and vacuum strength, which are usually now standard features of pumps (Eglash 2015; Wambach 2015).

Some babies are unable to feed at the breast, or consistently feed poorly, for example as a result of infant illness or prematurity. Breast milk expression is critical for these infants and their mothers, as it provides the only way for mothers to establish and/or maintain a breast milk supply (Cregan 2002; Harris 2014). Feeding with expressed breast milk is widely considered as a best alternative feed for babies who cannot feed at the breast (Divya 2016).

In the early postnatal period, it is common for new mothers to run into problems with attachment and/or supply. Breastmilk expression provides an interim way of managing these difficulties and may enable continued breastfeeding for these mothers and their infants (Felice 2017; Geraghty 2013; Wagner 2013). If breastmilk expression is difficult in the early days of the infant's life, a mother may give up on breastfeeding, with long term adverse impacts on her and her infant's health. As Becker (2016), has noted, reports on the economic aspects of breastfeeding have highlighted additional costs for families associated with not breastfeeding, related to increased infant illness, the need for caregivers to take time off work, and increased hospitalisation of infants (Becker 2016).

There are also some mothers who never intend to put their baby to the breast, though they believe in the benefits of breast milk and therefore wish to express milk to provide to their infant (Bai 2016; Keim 2017).

Breastmilk expression enables fathers and other caregivers of breastmilk fed infants to be involved in feeding, even soon after birth. It also enables mothers to be away from their babies, including for work, or due to sickness, without compromising the goal of achieving exclusive or partial breastfeeding (Felice 2017; Weisband 2017). Whilst a less common reason for the importance of breast milk expression, expression is required by some mothers who are preparing for adoptive or surrogate motherhood who want to express to facilitate providing milk for the baby (Auerbach & Avery 1981; Wittig & Spatz 2008).

Expressing may be necessary in some countries to heat treat human milk as a means of deactivating HIV (Wambach 2015; Israel-Ballard 2007). There are 17.8 million women world-wide living with AIDS, the largest proportion of whom live in Africa (Avert 2018; UN Women 2018). Pasteurization enables women to give their infants the benefits of breast milk without further endangering their infant's health (Wambach 2015).

Breastmilk expression is also relevant for safe sharing of breastmilk, and breast milk banks. A woman may choose to express if she would like to become a breast milk donor. Pasteurized donor breast milk is considered by the World Health Organisation (WHO 2003; WHO 2011) to be the next best and safest alternative to a mother's own breast milk, even though some immunological constituents will be reduced with pasteurization (Groer 2014; Peila 2016;

Quigley 2018). In Australia, there has been a rise of donor milk banks across the country since 2006 (Lording 2006), with the latest opening at the Women's and Children's Hospital and Flinders Medical Centre in September 2018 (South Australia), managed by the Australian Red Cross (Wade 2018).

Research on human milk, the pathways through which it impacts on infant health, and how to use better to promote infant health, requires samples of milk and women who express breastmilk to facilitate such research make a highly contribution to better knowledge.

An Australian review performed in 2006 (Binns 2006) showed that breastmilk expression is prevalent and had almost doubled over the previous decade. A study conducted in the USA observed that 85% of mothers expressed at least once in the first 4 months since birth (Labiner-Wolfe 2008). Another study, performed in China, showed 64% of women as expressing milk at least once during the first six weeks after birth (Jiang 2015).

The first weeks of milk production post birth and how it is managed predict long term breast milk supply, particularly with respect to the preterm infant population (Hill 2001; Hill 2005; Hoban 2018; Morag 2016). Whilst it is generally accepted that breastmilk expression impacts favourably on a mother's ability to achieve and sustain a long run breast milk supply, the details of how breastmilk expression positively effects long term milk production are not fully understood (Felice 2017; Johns 2013).

Barriers to effective breastmilk expression

Potential barriers to acceptable and effective breastmilk expression include lack of mother's confidence and knowledge about how to express, maternal illness, maternal stress, inadequate access to equipment or high cost of equipment, lack of privacy or space to express, and lack of social support (Becker 2016; Fabiyi 2015; Ikonen 2016; Nickel 2013; Yi 2016).

Studies have suggested these barriers to breastmilk expression are experienced more frequently in mothers of preterm infants, who are trying to establish effective breastmilk expression, whilst their preterm babies are learning to suck and breastfeed (Ikonen 2016; Lucas 2014; Nyqvist 1999). This is reflected in low exclusive breastfeeding rates at discharge for mothers of preterm infants (of around 55%), compared to mothers of term infants (around 72%) (Dodrill 2008; Kelly 2012).

Lack of evidence-based guidelines on breastmilk expression has been identified as a barrier to effective and acceptable breastmilk expression practices (Collins 2016; Goodchild 2018; Rodrigo 2018). Inadequate guidelines at the hospital level have also been identified as a contributor to the variations in practice that have been observed in small breastmilk expression practice audits in hospitals (Collins 2016; Goodchild 2018; Rodrigo 2018).

In summary, whilst breastfeeding has long been recommended as the gold standard for infant feeding, breastmilk feeding via expression may be the next best or only alternative to establish and maintain lactation, and thereby support optimal infant health. There are a variety of reasons why mothers may need or want to express milk for their babies, and studies suggest that breastmilk expression is prevalent and has been increasing. Whilst expressing breast milk is an important skill mothers to master in the early postnatal period, there are several factors that may make effective and acceptable breastmilk expression difficult, compromise a mother's lactation goals, and may lead to a decision not to continue with breastmilk feeding. This will impact negatively on the health of the infant, in particular if the infant is premature or sick.

1.2 Breastmilk expression interventions and how they might work

Expression of breastmilk interventions are complex, and many. Scoping of the literature identified a range of diverse interventions with the potential to support effective breast milk expression for mothers of new-born and older infants. Non-pharmacological interventions can be categorised into three types:

- 1) pumping equipment and method (e.g. pump, hand expression);
- 2) protocols relating to timing of expression (initiation, frequency, duration) and/or technique (e.g. pressure); and
- 3) education and support.

Pumping equipment and method

The intervention of hand expression is achieved through compressing ducts within the breast towards the nipple. The act of compression, aided by the hormone, oxytocin, squeezes the myoepithelial cells surrounding the ducts, releasing milk into the ducts and out of the nipple (Merewood & Morton 2013; McNeilly 1983; Weitzman 1980). The mechanism of hand expression compared to that of an electric pump has been speculated to result in slightly higher levels of sodium (Lang 1994), increased colostrum yield in the early days post-birth (Ohyama 2010; Vasan 2004), milk transfer on the day of hospital discharge (Vasan 2004) and possibly positively affects continuation of breastfeeding (Dewey 1986). Hand expression combined with the use of an electric breast pump has been suggested to positively affect breast milk yield (Lussier 2015; Morton 2009) and may or may not show a difference in breast milk nutritional content (Green 1982; Mangel 2015). Hand expression compared to manual and electric pumps may affect quantity of milk expressed (Pessoto 2010; Slusher 2007), bacterial counts, nutritional content of milk (Pessoto 2010) and oxytocin/ prolactin levels (Zinaman 1992).

With a manual pump, milk is released through either negative and/or positive pressure (usually through a piston mechanism) which is repetitively activated by the mother. As above, the oxytocin hormone and compression actively squeezes the myoepithelial cells releasing milk into the ducts and out of the nipple (Bachman 1995; Lawrence 2016; Renz 2003). By contrast, the electric pump combines compression and/or vacuum patterns (cycles) and suction strength (Alekseev 2016; Lawrence 2016; Kent 2008; McNeilly 1983; Weitzman 1980).

Different types of manual pump may produce differences in milk volume, milk content, time needed to express and maternal preference (Bernabe-Garcia 2012). Lactogenesis stage II, is the initiation of copious secretion of breast milk after delivery (Neville 1984). It is a complex physiologic phenomenon that may be affected by a number of factors, including maternal hormonal milieu, delivery mode, infant suckling, maternal nutritional status, and psychobiologic stress. When a manual pump is compared to an electric pump this may affect volume of milk (Fewtrell 2001b; Green 1982), time to lactogenesis II (Rasmussen 2011), bacterial counts (Pittard 1991), milk content (Boutte 1985) and breastfeeding duration (Hayes 2008). Interventions comparing two or more different electric pumps may affect milk weight, duration of expressing, maternal acceptability (Burton 2013), milk volume and time taken to express milk (Francis 2008).

Even aspects of a pump's equipment may affect total milk volume expressed per session, and maternal ease and comfort, such as the size of the nipple flange which the breast is placed in before expressing begins. Nipple/areola sizes differ between women and if the flange is too

small, there is a possibility of maternal pain/discomfort which may affect the new mother's stress levels and may impede the mechanical aspect of physically getting milk out (Jones 2009; Wambach 2015).

Instruction/education and support

Education regarding expressing may be provided antenatally and/or postnatally. Provision of breast milk expression education has been hypothesised to increase breast milk expression frequency, increase volume of milk expressed and reduce maternal stress levels (Gonzalez 2003; Sisk 2006), differences of lipid content and affect levels of maternal acceptability (Feldman 2003; Larque 2002; Sisk 2006). An observational study of peer/family support and/or education including use of breast pumps showed that this intervention increased breastfeeding duration (Chen 2012).

Other forms of support, such as **meditation** or relaxation exercises/music, breast warmth, breast massage and reflexology have also been identified as possibly enhancing milk flow, by stimulating oxytocin and reducing cortisol (Lawrence 2016; Jackson 2010; Wambach 2015). The intervention of meditation and or music may improve milk volume and milk content (Jackson 2010) whilst breast warmth facilitates improved breast milk flow and efficiency through stimulation of the 'let-down' reflex as heat is applied to the breast (Kent 2008; Yigit 2012). Breast massage can be performed before or during a feed and may increase breast milk volume and affect breast milk constituents (Foda 2004). In reflexology, the massaging of the breast/pituitary pressure points on the foot has been suggested to increase breast milk volume and reduce maternal stress/anxiety levels (Tiran 2010).

Protocols relating to timing of expression and/or technique

During literature scoping, there were several interventions identified with respect to expressing protocols with the potential to affect pumping outcomes.

The earlier the initiation of breast milk expression post birth for mothers of preterm infants, the higher the breast milk supply over time (Hopkinson 1988). This premise has been based on various studies highlighting a positive relationship between birth, time to first breastfeed and effects on breast milk production and infant morbidity/mortality in the term infant population (Hopkinson 1988; NEOVITA study group 2016; Salariya 1978).

WHO currently recommends term infants experience skin to skin contact immediately after birth and breastfeed within one hour (WHO 2017). In a study looking at breast milk output, Hill (2005) noted no lactating mothers of preterm infants were able to initiate breast expression within one hour of birth compared to 58% of term infants in the same study who had initiated breastfeeding within that time frame. More recent observational evidence suggests the most optimal time for initiation of first expression for mothers of preterm infants may be anywhere from one to six hours post birth to obtain the highest yield of colostrum (Ikonen 2018; Parker 2012).

Frequency of expression has been associated with the timing of the first breast expression with respect to increased milk outcomes (Hill 2001). High frequency breast expression, even as a stand-alone intervention (7 times per day versus 4 times per day), may result in higher milk weight (Hill 2001). Observational studies in term and preterm populations have consistently shown the higher the frequency of breast stimulation, the higher the volume of breast milk output (De Carvalho 1985; Egli 1961; Hill 1995; Yamauchi 1990). In a full-term scenario, the infant would most likely be feeding on demand and frequently according to the infant's own appetite and growth needs (Egli 1961; Yamauchi 1990). The BFHI guidelines of

6 to 8 expressions per day are based on the average amount of breastfeeds a term breastfeeding infant may feed per day (Kent 2006; WHO 1998; WHO 2009; Yamauchi 1990).

Recommended protocols for the duration of each breast milk expression session are not consistent. Suggestions include either 5 to 10 minutes on each breast, ceasing after a certain amount of milk is expressed, or ceasing when milk flow stops. (Bernabe-Garcia 2012; Burton 2012; Fewtrell 2001a; Fewtrell 2001b; Meier 2012). The BFHI training manual for health professionals recommends 5 to 10 minutes when extracting colostrum and for breastmilk, 15 to 30 minutes once supply is established (WHO 2009).

Double pumping means pumping both breasts at the same time to express milk. Double pumping is widely understood to increase breast milk volume (Auerbach 1990; Groh-Wargo 1995; Hill 1999; Koroglu 2017) and some have suggested it increases the fat content of the expressed milk (Auerbach 1990). Double pumping has also been reported to increase maternal satisfaction with pumping, (Koroglu 2017), which may be because in most women it makes expression more efficient (i.e. reduced time taken to express) (Prime 2012).

Additionally, electric breast pump features such as varying pressures either pre-set within the pump or set by the mother (dials on the machine) to replicate a term infant's varying suck/swallow patterns an intervention that may influence amount and quality of milk expressed (Woolridge 1986; Webber 1986). Breast pumps with suction pressures adjusted to how an infant would feed on the breast may result in higher volumes of breast milk which may lead to maternal preference (Meier, 2012).

Potential modifiers of effects and acceptability

Mothers may have different levels of motivation to express breastmilk, and express for different reasons, depending on their situation. Scoping of the literature identified the following factors as potential modifiers of breastmilk expression intervention effects or acceptability (see Becker 2016; Ikonen 2017): gestational age at birth, time since birth, health of the women expressing milk (including psychological health and stress level), and mode of birth (caesarean section versus vaginal birth).

1.3 Definition and importance of RCT and systematic review evidence

Randomised controlled trials (RCTs) are experimental research studies designed to address questions about the effects of interventions or procedures. In the RCT, the unit of experimentation (e.g. people, or a cluster of people) is allocated to either an intervention (the factor under study) group or a control group, using a random mechanism (such as a coin toss, random number table, computer-generated random numbers) and the outcomes from each group are compared. (NHMRC 2009). Randomisation of participants to the comparator groups minimises differences between the characteristics of the groups compared (aside from the intervention), making it likely that difference (s) observed in outcomes are due to the intervention, and will be replicated if the same intervention is implemented again, at least in in population and setting with similar characteristics.

Findings generated by RCTs are regarded by decision makers working in health care, including health professionals who provide care and those working on the development of clinical guidelines and policy to promote minimum standards and uniform care across setting, as the most trustworthy evidence for questions about intervention effects (NHMRC 2009; Gomersall 2015).

However, the conduct of RCTs varies; the results of some RCTs are not reliable due to randomisation being broken or other failures to follow protocol. Appraising the quality of

RCTs requires a certain level of knowledge on research methods and tools commonly used to appraise this type of research. Accessing relevant RCTs can be resource intensive, due to the need to pay for electronic database access, learn how to search these appropriately, and in some instances, the large number of trials published. Systematic review methodology emerged in the 1970s as a response to decision makers' need for summaries of the available RCT evidence on the effects of emerging new technologies and proposed interventions for improving health outcomes, and difficulties experienced in accessing, assessing and interpreting studies. The systematic review is a collation of all empirical evidence that fits pre-specified eligibility criteria aimed at answering a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made (Higgins 2001; or available online at <https://community.cochrane.org/handbook>). The NHMRC (2009) has defined systematic review as: systematic location, appraisal, and synthesis of evidence from scientific studies (refer to Appendix 1 for the NHMRC description of types and quality levels (I-IV, lower is better) for evidence addressing questions about intervention effects).

The systematic review performed in this research project followed Cochrane methods, as outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011, or available online at <https://community.cochrane.org/handbook>) and as presented in a workshop attended by the author in 2018. The key characteristics of a systematic review are described in the Cochrane Handbook for Systematic Reviews of Interventions as: a clearly stated set of objectives with pre-defined eligibility criteria for studies; an explicit, reproducible methodology; a systematic search that attempts to identify all studies that meet the eligibility criteria; an assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias; and a systematic presentation, and synthesis, of the characteristics and findings of the included studies.

Systematic reviews may contain meta-analyses, a statistical method that summarizes the results of independent studies contributing data on the effects of the same intervention, for the similar outcome measures. Such analysis adds value, as it combines the information from all relevant studies on the effects of an intervention on a particular outcome, offering a more precise estimates of the effects than the effect estimate derived from an individual study, or studies included within a review. Meta-analyses facilitate investigations of the consistency of evidence across studies, and the exploration of differences across studies (e.g. via subgroup analyses).

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for assessing the certainty in the body of health evidence for a particular intervention/technology has become a cornerstone of systematic reviews addressing question of intervention effects (Guyatt 2008 & 2011; Santesso 2016). This involves assessing the trials contributing results to the review meta-analyses (for each intervention assessed), for selected outcomes (judged critical or important by the reviewers, up to seven outcomes), based on five considerations. The considerations, frequently labelled domains, are: risk of bias/study limitations; consistency of effect; imprecision; indirectness; and publication bias (Schunemann 2013). **GRADE** uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. Evidence from RCTs starts as 'high quality', and may be **downgraded** by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. The grade assigned to the body of evidence for each outcome and comparison is reported, with the reasons for downgrading, in the Summary of Findings (SOF) tables, providing users of the systematic review with an easily understandable interpretation of the best available evidence about the effects of the

intervention(s) assessed in the systematic review, organised by the selected outcomes. The GRADE grades of evidence, that can be awarded to the body of evidence for each of the selected outcomes assessed in the systematic review are summarised below.

⊕⊕⊕⊕ *high quality*: further research is very unlikely to change our confidence in the estimate of effect

⊕⊕⊕⊖ *moderate quality*: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate

⊕⊕⊖⊖ *low quality*: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

⊕⊖⊖⊖ *very low quality*: we are very uncertain about the estimate

Literature on systematic review methodology indicates that it is important for systematic reviews aimed at informing clinical guidelines to be conducted by review teams that include experts in systematic review methods and with relevant clinical knowledge. The involvement of clinical experts who are working is important not only to inform relevant outcomes for evaluation, but also to facilitate translation of the findings from systematic review into guidelines and practice (Møller 2016; Pearson 2012).

1.4 Objective

Primary objective:

To identify and evaluate the best available RCT evidence on effective and acceptable methods of breastmilk expression for lactating mothers and their infants.

Secondary objective:

To inform research priorities and best practice guidelines relating to breastmilk expression for lactating mothers and their infants.

Chapter 2: Methods

2.1 Research question

Primary

What are effective and acceptable methods of breast milk expression for lactating mothers and their infants?

Secondary

What research priorities and recommendations for practice, are informed by the available RCT evidence on effective and acceptable methods of breast milk expression for lactating women?

2.2 Review eligibility criteria

Types of participants

- Women expressing or pumping milk any time after birth, located in any country and type of hospital (or other type of health service) and community setting, who may or may not also be feeding a child at the breast.
- Term and/or preterm infants, singles or multiples.

There were no restrictions on health status of mother or child.

Types of interventions

All types of non-pharmacological interventions to enable effective and acceptable breast milk expression were eligible including: 1) pumping equipment and method (e.g. pump, hand expression); 2) protocols relating to timing of expression (initiation, frequency, duration) and/or technique (e.g. pumping pressure) and 3) education or support specific to breastmilk expression.

Single and combined interventions were eligible.

Interventions aimed at promoting breastfeeding (e.g. breastfeeding education and support) were included only if the intervention included a component specifically targeted at enabling breastmilk expression).

Types of comparator interventions

- 1) Standard care
- 2) Any of the eligible breast milk expression interventions, as single or combined interventions.

Primary

- Quantity of milk expressed (all time points and measures reported)
- Quality of milk expressed (e.g. nutrient, fat, energy content in milk)

- Maternal satisfaction (or lack of maternal satisfaction) with method including acceptability, comfort, ease of use and achievement of woman's goal(s) for expressing or pumping

Secondary

Feeding

- Breastfeeding (rates, at discharge and other time points up to six months, and duration)
- Transfer to feeding at the breast
- Time of initiation of breast milk expression or feeding
- Maternal physiological effects of expressing or pumping (e.g. time to lactogenesis stage II, prolactin and other hormone levels)

Maternal health

- Depression, anxiety and stress measures
- Other wellbeing measures

Infant health

- Growth
- Length
- Head circumference

Adverse effects for mother or infant

- Contamination of expressed breastmilk e.g. bacterial level in expressed milk (Dornic degrees of acidity)
- Reduction or cessation of pumping or expressing due to difficulties with pumping or expressing
- Other (e.g. nipple pain, engorgement, damage to the breast)

Acceptability

- Time taken to express milk
- Infant length of hospital stay
- Cost: of pumping equipment (for mother/family); to healthcare facility of supporting expression method/pump equipment, protocol or education and support

We expected variation across the included studies in the outcome measures used and planned to consider all measures for which an evidence-based rationale was provided.

Types of studies

Following standard practice for systematic review to inform guidelines, we planned to include the highest level of evidence in the NHMRC evidence classification system (NHMRC 2009, see Appendix 1).

During literature scoping for this research project, we identified a systematic review published in the [Cochrane Library](#) addressing the our planned research question, with the same population, intervention, comparator and outcome inclusion criteria. This review, by Becker et al (Becker 2016), has a last search update of 31st March 2016. The review, titled “*Methods of milk expression for lactating women (Review)*”, published in 2016 Issue 9 in the *Cochrane Database of Systematic Reviews*, included 41 randomised controlled trials (RCTs). In addition, we identified more RCTs published since last date for inclusion in the Becker 2016 review.

We therefore included the Becker 2016 systematic review and defined the type of studies eligible for additional inclusion as:

- 1) RCTs published since the date of the last search for the Becker 2016 review; and
- 2) reports of RCTs included in the Becker 2016 review reporting relevant outcomes data not included in the Becker 2016 review.

We considered individual and cluster RCTs, and cross-over trials. Abstracts were considered for inclusion, provided they reported at least one outcome (narrative or quantitative data).

We excluded non-English reports of studies. **Including non-English studies was not feasible due to limited resources.**

We developed a population, intervention, comparison and outcome (PICO) inclusion criteria table to guide the selection of studies and minimise bias during study selection and data extraction (see PICO table in Appendix 2).

2.3 Search strategy

Literature scoping

The scoping searches, performed between January and March 2018, aimed to identify systematic reviews and primary studies of all design types.

The databases searched during scoping included: Cochrane Central; TRIP; Web of Science; Medline; JBI; CINAHL; Psych Info; Informit Health; Embase; Scopus; PubMed; and Google Scholar.

We used the search terms: “breast milk”, express*, pump*, “breast milk express*”, “breast milk pump*”, “breast massage”, relaxation, meditation, relaxation AND “breast milk express*” OR “breast milk pump*”, meditation AND “breast milk express*” OR “breast milk pump*”, warmth AND “breastmilk express*” OR “breast milk pump*”, education OR instruction OR teaching OR education AND “breast milk express*” OR “breast milk pump*”, sequential OR single AND simultaneous OR double AND “breast milk express*” OR “breast milk pump*”, “hand express*” OR “manual express*” OR “manual pump*” OR “electric breast pump*”, suction AND “breast milk pump*” OR “breast milk express*”

Search to update the Becker 2016 systematic review

Electronic database searches

We searched Cochrane Central (5 July 2018), CINAHL (5 July 2018), Embase (5 July 2018), Scopus (5 July 2018), and PubMed (15 July 2018) to identify potentially relevant RCTs not included in the Becker systematic review, and secondary papers of RCTs included in the Becker review with potentially relevant data. Table 1 provides the search terms used for each database. The search terms were standardised as far as possible across the databases.

Table 1: Searches to retrieve records from electronic databases

Database	Date of search	Search terms
PubMed	13 th July 2018	breast milk expression'/de OR 'breast milk express*':ti,ab OR 'breastmilk express*':ti,ab OR breastpump*':ti,ab OR 'breast pump*':ti,ab OR 'breast milk collect*':ti,ab OR 'breastmilk collect*':ti,ab OR 'electric pump*':ti,ab OR 'manual pump*':ti,ab OR 'breast express*':ti,ab OR 'expressed breast milk':ti,ab OR 'expressing breast milk':ti,ab OR 'expressed breastmilk':ti,ab OR 'expressing breastmilk':ti,ab OR 'pumping breastmilk':ti,ab OR 'pumping breast milk':ti,ab OR 'pumped breastmilk':ti,ab OR 'pumped breast milk':ti,ab OR 'pumped milk':ti,ab OR 'manual express*':ti,ab OR 'hand express*':ti,ab OR vacuum:ti,ab OR 'milk ejection' OR 'milk, ejection' OR 'breast milk' OR 'breast milk volume':ti,ab 'randomised controlled trial' OR 'randomized controlled trial' #1 AND #2 AND #3 #4 AND ('human'/de OR 'randomized controlled trial'/de) AND (2016:py OR 2017:py OR 2018:py)
CINAHL	5 th July 2018	"milk, human" OR "breast feeding" OR breastfeeding OR "milk expression" OR TI "breast milk expression" OR AB "breast milk expression" OR TI "milk expression" OR AB "milk expression" OR "breast pumps" OR TI "electric pump" OR TI "electric pump" OR TI "manual pump" OR AB "manual pump" OR TI "hand express" OR AB "hand express" OR vacuum OR suction OR TI "let down" OR AB "let down" OR TI "milk ejection" OR AB "milk ejection" Search with AND "prenatal care" OR "childbirth education" OR TI "postnatal education" OR AB "postnatal education" OR "postnatal care" OR "muscle relaxation" OR relaxation OR "relaxation techniques" OR massage OR music OR "lactation consultants" OR "mobile applications" OR reflexology OR homeopathy OR "alternative therapies" OR TI "sequential pumping" OR AB "sequential pumping" OR TI "simultaneous pumping" OR AB "simultaneous pumping" OR TI initiation OR AB initiation OR TI frequency OR AB frequency OR TI "times per day" OR AB "times per day" OR TI "time taken to express" OR AB "time taken to express" OR TI "until the flow stops" OR AB "until the flow stops" OR TI duration OR AB duration OR TI timing OR AB timing OR TI warmth OR AB warmth OR TI length OR AB length OR TI instruction OR AB instruction OR "social support" OR counselling OR "health promotion" (manual limits of date restrictions 2016 to 2018, humans, English) NOT LIMITED TO RCTs
Embase	5 th July 2018	breast milk expression'/de OR 'breast milk express*':ti,ab OR 'breastmilk express*':ti,ab OR breastpump*':ti,ab OR 'breast pump*':ti,ab OR 'breast milk collect*':ti,ab OR 'breastmilk collect*':ti,ab OR 'electric pump*':ti,ab OR 'manual pump*':ti,ab OR 'breast express*':ti,ab OR 'expressed breast milk':ti,ab OR 'expressing breast milk':ti,ab OR 'expressed breastmilk':ti,ab OR 'expressing breastmilk':ti,ab OR 'pumping breastmilk':ti,ab OR 'pumping breast milk':ti,ab OR 'pumped breastmilk':ti,ab OR 'pumped breast milk':ti,ab OR 'pumped milk':ti,ab OR 'manual express*':ti,ab OR 'hand express*':ti,ab OR vacuum:ti,ab OR 'milk ejection' OR 'milk, ejection' OR 'breast milk' OR 'breast milk volume':ti,ab 'randomised controlled trial' OR 'randomized controlled trial' #1 AND #2 AND #3 #4 AND ('human'/de OR 'randomized controlled trial'/de) AND (2016:py OR 2017:py OR 2018:py)
Scopus	5 th July 2018	In basic search type in "breast milk expression" OR "breast milk volume" OR "breast pump" OR "hand expression" OR "breastfeeding" OR "breast feeding" OR "human milk" AND "24nglish24ed controlled trials" OR "randomized controlled trials" Limit tab 2016 to 2018, press search. Upon results additional manual limits of human, 24nglish and RCT's on left hand side of screen. Press limit to icon
Cochrane CENTRAL	5 th July 2018	breastmilk expression or "breastfeeding" or "breast feeding" press search then manually apply 2016 to 2018 date limit

Search of other resources

We performed a hand search of the journals *Breastfeeding Review*, *Journal of Human Lactation*, *International Breastfeeding Journal*, and *Breastfeeding Medicine*.

We created online alerts on May 2018 in: NCBI (PubMed), Scopus, Embase, Ovid Medline, Web of Science and CINAHL.

Where necessary trial authors were emailed for additional information during full text review. Five trial authors were contacted.

2.4 Data collection and analysis

Screening of titles and abstracts

One reviewer imported the records identified by the electronic and hand searchers into Endnote and used the Endnote duplicate function to remove duplicates. Two reviewers screened the remaining records, working independently, and guided by a screening tool informed by the eligibility criteria.

Retrieval and screening of full text articles

The articles for full text review were imported into EndNote (version 7) by one reviewer. Two reviewers independently screened the full texts, excluding those that did not meet the inclusion criteria, and recording the reasons for exclusion. Conflicts were resolved through discussion. We planned to consult with a third reviewer if conflicts were not resolvable, however this was not necessary.

Data collection and management

We designed a form to extract data. For eligible trials, two review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted a third review author.

Outcomes data were entered in Review Manager software (RevMan 2014) by one reviewer.

Assessment of risk of bias in included studies

Systematic review

Risk of bias (ROB) in the included systematic review was assessed using the ROBIS tool (Whiting 2016). Two reviewers performed the assessment, working independently, resolving discrepancies through discussion.

Primary studies

Two reviewers independently assessed the risk of bias in the included RCTs using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (version 5.1; Higgins 2011). The reviewers worked independently, and then met to compare results, discuss and resolve differences in judgements.

- (1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. We assessed the method as:

- Low risk (any truly random process, e.g. random number table; computer random number generator);
- High risk (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- Unclear risk (insufficient information to permit the judgement of low or high risk).

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the methods used to conceal the allocation sequence and determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. When studies did not report any concealment approach, they were considered unclear. We assessed methods as:

- low risk (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk (insufficient information to permit the judgement of low or high risk)

(3a) Blinding of participants and personnel (checking for possible performance bias)

We considered that due to the nature of the interventions evaluated, blinding of mothers or their carers to the interventions was generally not plausible. For each trial we identified whether blinding would have been feasible. We assessed all studies for performance bias as:

- low risk (no or incomplete blinding but the review authors judge that the outcome is not likely to be influenced; blinding of study participants and personnel ensured and unlikely that the blinding could have been broken);
- high risk (outcome is likely to be influenced by no or incomplete blinding; blinding of study participants and personnel attempted, but likely that the blinding could have been broken and the outcome is likely to be influenced by lack of blinding);
- unclear risk (insufficient information to assess the risk of bias or the study did not address this outcome).

(3b) Blinding of outcome assessment (checking for possible detection bias)

We described for each study the methods used, if any, to blind outcome assessors from the knowledge of which participant actually received the intervention. Blinding was appraised independently for different outcomes or levels of outcome. We assessed the methods as:

- Low risk (no blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; or blinding of outcome assessment ensured, and unlikely that the blinding could have been broken);

- high risk (no blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; or blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding);
- unclear risk (insufficient information to permit judgement of 'low risk' or 'high risk; if the outcome was not reported in the study, or clarity was not obtained through communication with the trialist when feasible).

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts and protocol deviations)

We indicated for each included trial, the completeness of the data including attrition and omission from analysis. We stated whether attrition and exclusions were reported, numbers included in data synthesis at each stage (compared to randomised participants), reasons for missing data or exclusions stated and whether absent data was balanced between groups or linked to outcomes. Where adequate information was reported or could be provided by study authors, missing data was included in the analysis. We assessed the methods as:

- Low risk (e.g. where there were no missing data or where reasons for missing data were balanced across groups);
- High risk (e.g. where missing data may have related to outcomes or were not balanced across groups);
- Unclear risk (e.g. where there was insufficient reporting of attrition or exclusions to permit a judgement to be made).

(5) Selective reporting bias

For each included trial, we investigated the possibility of selective outcome reporting bias. We assessed the methods as:

- Low risk (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- High risk (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- Unclear risk (where we were unable to confidently assess the trial as low risk or high risk of bias, due for example to inability to access the protocol for the study).

(6) Other sources of bias

In the notes section of Characteristics of included studies table, for each study we recorded any other concerns about bias such as source of funding, any significant deviation from the study protocol, or serious baseline imbalance. We assessed whether each study was free of other problems that could put it at risk of bias:

- Low risk (study appears to be free of other sources of bias);
- High risk (at least one important risk of bias, e.g. had a potential source of bias related to the specific study design);
- Unclear risk (insufficient information to assess whether an important risk of bias exists or insufficient rationale or evidence that an identified problem will introduce bias).

Assessment of the quality of the evidence using the GRADE approach

For selected outcomes, we planned to assess the quality of the evidence using the GRADE approach, as outlined in the GRADE handbook (Schünemann 2013). We also planned to create 'Summary of findings' (SoF) tables reporting the results of these analyses, with the assistance of the GRADEpro Guideline Development Tools.

The outcomes selected for the GRADE analyses were the following:

1. Maternal satisfaction
2. Quantity of expressed milk
3. Quality of expressed milk
4. Breastfeeding (rate)
5. Breastfeeding duration
6. Reduction or cessation of pumping or expressing due to difficulties with pumping or expressing
7. Contamination of expressed breastmilk

We were unable to perform GRADE analyses to due lack of data, and more specifically, only one study was available for inclusion in analyses, with the exception of one quantity of milk outcome measure in a single comparison.

Measures of treatment effect

Dichotomous data

For dichotomous data we presented results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, the results were presented as mean difference with 95% confidence intervals.

Unit of analysis issues

Cluster randomised trials

We planned to include cluster-randomised trials in the review meta-analyses along with individually randomised trials, adjusting data from these trials using the methods described in

the Handbook (Section 16.3.4 or 16.3.6). More specifically, we planned to use an estimate of the intra-cluster correlation co-efficient (ICC) derived from the trial if possible, from a similar trial or from a study of a similar population, and the average cluster size reported by the study, to compute a design effect adjustment factor using the following formula:

$$\text{Design effect} = 1 + (M-1) \times \text{ICC}$$

If we used ICCs from other sources, we planned to report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. For each of the dichotomous outcomes reported by cluster trials, we planned to divide the number of participants and events of both groups by the computed design effect. For each continuous variable reported, we planned to adjust the sample size of the two groups by the design effect.

We included one cluster randomised trial in the review. See Appendix 3 for the details on the computation of the design effect for this trial.

Studies with more than two intervention groups (multi-arm trials)

For included multi-arm trials, we used methods described in the Cochrane Handbook for Systematic Reviews of Interventions to overcome possible unit of analysis errors (Higgins 2011), by combining groups to make a single pair-wise comparison (where appropriate), or by splitting the 'shared' group into two (or more) groups with smaller sample sizes and including the two (or more) comparisons.

Cross-over trials

Cross-over trials were included for this update of the review, if deemed eligible, along with parallel group trials in the analyses, using the methods described in the Cochrane Handbook (Higgins 2011). We did not include unpaired data from cross-over trials in the analyses, as we sought to use only paired data such that information would be available regarding the within-mother comparison of methods of milk expression. In instances where cross-over trials only reported on unpaired data, we elected to report these as narrative outcomes.

Dealing with missing data

For included trials, we noted levels of attrition. For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, that is, we have attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We planned to assess statistical heterogeneity in each meta-analysis using the Tau^2 and Chi^2 statistics. Heterogeneity was regarded as substantial if the T^2 was greater than zero and either an I^2 was greater than 30% or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting bias

Had we included 10 or more studies in any meta-analysis, we would have investigated reporting biases (such as publication bias) using funnel plots. We would have assessed funnel

plot asymmetry visually. If asymmetry was suggested by a visual assessment, we would have performed exploratory analyses to investigate it. However, we were unable to include more than 10 studies in any meta-analysis due to the high level of variation across the studies included in this review, in the interventions and comparisons assessed.

Data synthesis

We used RevMan 2014 for the statistical analysis. We downloaded the RevMan data file containing the Becker 2016 systematic review data and analysis from the Cochrane library. We then added the data to the RCTs identified as updates to the Becker review to this data file (to relevant comparisons or if necessary new comparisons, that we created).

Due to one study only being included in each analysis (except for the analysis for one outcome, which included only two studies), fixed effect meta-analysis was performed for all the comparisons and outcomes.

We displayed the synthesis data, as the average treatment effect with 95% confidence intervals. Had we used random-effects analyses, we would have presented the results as the average treatment effect with 95% confidence intervals, and the estimate of Tau^2 and I^2 .

Sensitivity analyses

We planned to repeat the overall analyses for the primary outcomes, excluding trials assessed as at high risk of selection or attrition bias, across all comparisons. These analyses were planned to explore the effect of trial quality on the direction and magnitude of our effect estimates. These were not able to be conducted due to lack of data.

Subgroup analyses and investigation of heterogeneity

We planned to investigate heterogeneity in subgroup analyses, consider whether an overall summary was meaningful, and if it was, use random-effects analysis to produce it. We planned to interpret the results of the subgroup analyses using the Chi2 statistics and P value, and the interaction test I^2 value. The planned subgroup analyses to explore heterogeneity were:

- *Gestational age at birth*: early preterm (< 34 weeks) versus preterm (34 to < 37 weeks) versus term (34 to < 37 weeks)
- *Time since birth*: ≤ 2 weeks versus $> 3 \leq 6$ weeks versus > 6 weeks
- *Health of woman expressing milk*: healthy versus not healthy (any health condition that may affect milk production, including psychological health and stress level, reported on medical record at time of birth)
- *Mode of birth*: (caesarean section versus vaginal birth)

We planned to perform the subgroup analyses for the primary outcomes and outcomes selected for GRADE evidence quality assessment. These analyses were not performed due to the small number of studies (either one or two) providing outcomes data for analyses.

Chapter 3: Results

3.1 Description of studies

Results of the search

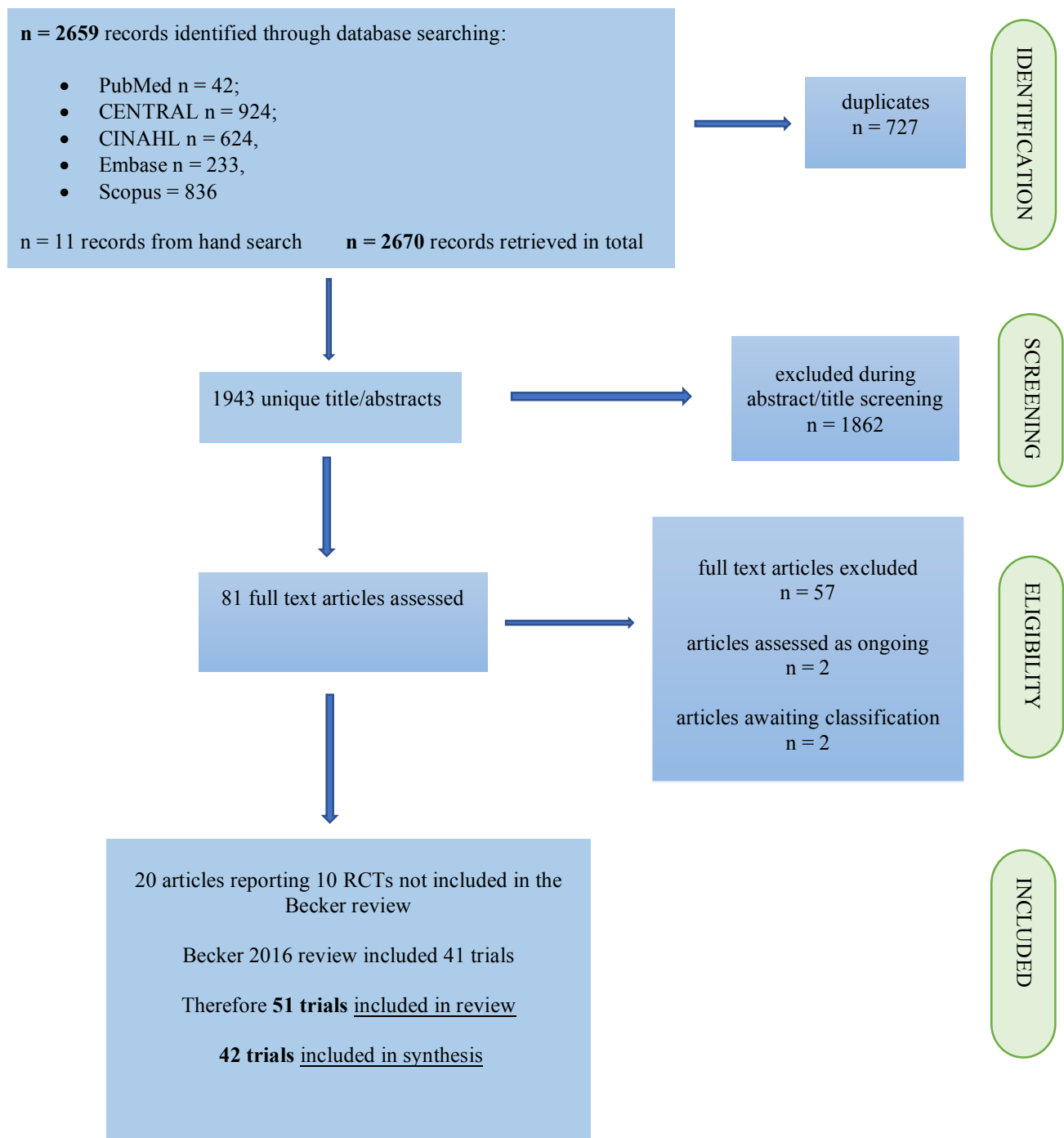
Scoping of the literature

Scoping of the literature identified one Cochrane systematic review (Pregnancy and Childbirth Group), conducted by Becker and colleagues (date of last search 21 March 2016) for inclusion.

Search to update the Becker systematic review

A total of 2670 records were identified from the electronic database searches to update the Becker review and hand search for screening; 726 of these records were identified by EndNote as duplicates, and were removed, leaving 1943 records for title/abstract screening. 1862 of these records were excluded during title and abstract screening, leaving 81 records for full text review. We excluded 57 of the full text articles, assessed two as ongoing, and classified two as awaiting classification. 20 articles reporting 10 RCTs not included in the Becker review were included (see Figure 1).

Figure 1: PRISMA diagram of search updating the Becker 2016 review



Included studies

Overall, 51 trials are included in this review, of which 41 were included in the Becker 2016 systematic review, and 10 are RCTs (Demirci 2016; Kennedy 2016; Lawrence 2017; McLachlan 2016; Mirzaie 2018; Mohammadpour 2018; Niela-Vilen 2016; Parker 2017; Steurer 2017; and Zhang 2017) updating the Becker 2016 review (see Figure 1). One of the included RCTs (Kennedy 2016) was classified as ongoing in the Becker review. One of the included trials (McLachlan 2016) was a cluster randomised trial (McLachlan 2016).

A total of 10 134 mothers and their infants were randomised in the 51 trials included in this review. McLachlan 2016 (the one included cluster randomised trial) was the largest trial, randomising 7039 women, followed by Parker 2011, randomising 184 women, Zhang, randomising 164 women, and Keith, randomising 162 women. Demirci 2016, Garza 1982, Mersmann 1993 and Stutte 1988 were the smallest trials randomising 11, 18, 18 and 18 women, respectively.

42 of the 51 included trials contributed outcomes (data or narrative) to the review synthesis (Ahmed 2008; Barnabe-Garcia 2012; Boo 2001; Burton 2013; De Carvalho 1985; Demirci 2016; Feher 1989; Fewtrell 2001a; Fewtrell 2001b; Flaherman 2012; Francis 2008; Garza 1982; Groh-Wargo 1995; Heon 2011; Hill 1999; Hopkinson 2009; Jones 2001; Kennedy 2016; Keith 2012; Lawrence 2017; Lusser 2015; Mangel 2015; Mclachlan 2016; Meir 2012; Mersmann 1993; Mohammadpour 2018; Mirzaie 2018; Niele-Vielen 2016; Parker 2012; Parker 2017; Paul 1996; Pesotto 2010; Pinelli 2001; Prime 2010; Prime 2012; Slusher 2007; Stellwagen 2010; Steurer 2017; Stutte 1998; Vasan 2004; Yigit 2012; Zhang 2017). A total of 9596 women and infants were randomised in the 42 trials that contributed to the synthesis.

For most trials that contributed outcomes data for the review synthesis, substantially fewer women were included in the analyses than were randomised, with a maximum of 1533 women included in review analyses.

Review structure

The review analysis is structured by the 19 comparisons reported, as follows.

PUMP versus HAND EXPRESSION

- *Any pump versus hand expression (analysis 1)*
- *Manual pump versus hand expression (analysis 2)*
- *Large electric pump versus hand expression (analysis 3)*
- *Hand expression for 7 days versus 3 days, prior to electric pump use (analysis 4)*
- *Breast massage versus no breast massage (analysis 5)*

TYPE OF PUMP/PUMPING EQUIPMENT

- *Manual pump versus another manual pump (analysis 6)*
- *Manual pump versus small electric hand-held pump (analysis 7)*
- *Type of battery/small electric pump (analysis 8)*

- *Large electric pump versus manual pump (analysis 9)*
- *Large electric pump versus battery/small electric pump (analysis 10)*
- *Simultaneous versus sequential pumping (analysis 11)*
- *Large versus small breast shield (analysis 12)*

INSTRUCTION/EDUCATION AND OTHER SUPPORT

- *Relaxation versus no specific relaxation (analysis 13)*
- *Relaxation versus another type of relaxation (analysis 14)*
- *Instruction and support versus no specific or other instruction and support (analysis 15)*
- *Warming the breast versus no warming (analysis 16)*

PROTOCOLS RELATING TO TIMING OR PUMPING TECHNIQUE

- *Any vacuum protocol versus another vacuum protocol (analysis 17)*
- *Time of initiation of breastmilk expression (analysis 18)*
- *Frequency of breast expression: ≥ 4 versus ≤ 3 times per day (analysis 19)*

Settings

The 51 trials included in this review were undertaken in a wide range of high, middle- and low-income countries. A total of 27 trials were performed in the USA, four were performed in the United Kingdom, three were conducted in Australia, two each were performed in Canada, Iran, and India, and one each in Brazil, China, Ecuador, Egypt, Finland, Malaysia, Mexico, Israel, and Turkey. The remaining two trials were multi-country trials: one was conducted in Kenya and Nigeria, the other in China, USSR, UK and USA.

Most of the included trials were conducted in NICUs of hospitals, however a few trials included mothers and infants in home settings.

Participants

Focusing on the 42 trials contributing outcomes to the synthesis in this review, all included mothers and their infant or infants. One of the trials Pinelli 2001, which evaluated instruction support intervention, included not only mothers and their infants, but also fathers of the included infants.

Two of the 42 trials contributing to the synthesis included singletons and multiples (Burton 2013; Hill 1999). Twelve of the 42 trials included singleton infants only (Barnabe-Garcia 2012; Fewtrell 2001b; Garza 1982; Groh-Wargo 1995; Heon 2011; Hopkinson 2009; Jones 2001; Lussier 2015; Parker 2012; Pessoto 2010; Pinelli 2001; Zhang 2017). The remaining trials did not report whether the included infants were singletons only or singleton and multiples (Ahmed 2008; Boo 2001; De Carvalho 1985; Demirci 2016; Feher 1989; Fewtrell 2001a; Flaherman 2012; Francis 2008; Kennedy 2016; Keith 2012; Lawrence 2017; Mangel 2015; McLachlan 2016; Meir 2012; Mersmann 1993; Mohammadpour 2018; Mirzaie 2018;

Niele-Vielen 2016; Parker 2017; Paul 1996; Prime 2010; Prime 2012; Slusher 2007; Stellwagen 2010; Steurer 2017; Stutte 1998; Vasan 2004; Yigit 2012).

Considering gestational age at birth of included infants, in ten of the 42 trials contributing outcomes to the synthesis, infants born at term (≥ 38 gestational weeks) were included only (Fewtrell 2001a; Flaherman 2012; Francis 2008; Garza 1982; Hopkinson 2009; Kennedy 2016; Mangel 2015; Prime 2010; Stutte 1998; Zhang 2017). Twenty-one of the trials included preterm infants only (Ahmed 2008; Barnabe-Garcia 2012; Burton 2013; De Carvalho 1985; Demirci 2016; Feher 1989; Fewtrell 2001b; Heon 2011; Jones 2001; Keith 2012; Lawrence 2017; Lusser 2015; Meir 2012; Mersmann 1993; Mohammadpour 2018; Mirzaie 2018; Niele-Vielen 2016; Paul 1996; Stellwagen 2010; Steurer 2017; Yigit 2012) (early preterm, i.e. <34 weeks and/or late preterm infants 34-37 weeks gestational age, others both). Eight trials specified that they included very low both weight babies, low birth weight babies or low weight babies and preterm infants (Boo 2001; Groh-Wargo 1995; Hill 1999; Parker 2012; Parker 2017; Pesotto 2010; Pinelli 2001; Vasan 2004). Three trials (McLachlan 2016; Prime 2012; Slusher 2007) did not report any details regarding gestational age at birth eligibility criteria for infant inclusion in the study.

Mode of birth was not reported by 40 of the 42 trials contributing outcomes to the review synthesis (Ahmed 2008; Barnabe-Garcia 2012; Boo 2001; Burton 2013; De Carvalho 1985; Demirci 2016; Feher 1989; Fewtrell 2001a; Fewtrell 2001b; Flaherman 2012; Francis 2008; Garza 1982; Groh-Wargo 1995; Heon 2011; Hill 1999; Hopkinson 2009; Jones 2001; Kennedy 2016; Keith 2012; Lawrence 2017; Lussier 2015; Mangel 2015; McLachlan 2016; Meir 2012; Mersmann 1993; Mirzaie 2018; Niele-Vielen 2016; Parker 2012; Parker 2017; Paul 1996; Pesotto 2010; Pinelli 2001; Prime 2010; Prime 2012; Slusher 2007; Stellwagen 2010; Steurer 2017; Stutte 1998; Vasan 2004; Yigit 2012). For the remaining two trials (Mohammadpour 2018; Zhang 2017) birth was by caesarean section.

Health of included mothers was poorly reported **by most of the 42** trials included in the review synthesis, with nineteen trials not reporting any information about the health of eligible women (Boo 2001; Burton 2013; Demirci 2016; Feher 1989; Fewtrell 2001a; Fewtrell 2001b; Francis 2008; Groh-Wargo 1995; Jones 2001; Kennedy 2016; McLachlan 2016; Niele-Vielen 2016; Parker 2017; Pinelli 2001; Prime 2010; Slusher 2007; Stellwagen 2010; Vasan 2004; Yigit 2012). Eleven trials included healthy women only, commonly reported as “with no medical conditions” in the trial eligibility criteria (Ahmed 2008; Barnabe-Garcia 2012; De Carvalho 1985; Garza 1982; Hopkinson 2009; Lussier 2015; Mangel 2015; Meir 2012; Mersmann 1993; Mirzaie 2018; Slusher 2007; Zhang 2017). In the remaining 11 trials (Heon 2011; Hill 1999; Lawrence 2016; Lussier 2015; Meier 2012; Mohammadpour 2018; Parker 2012; Paul 1996; Pessoto 2010; Steurer 2017; Stutte 1998), health of included women was mixed with some of these trials having specific excluded health conditions (e.g. HIV status, prior breast surgery, mastitis/breast engorgement, no injury on feet, no history of thyroid or other endocrine disorders). Parker 2012 excluded women with HIV or/and a record of breast surgery. Paul 1996 included women who were well enough to visit feeding room and already expressing prior to the start of the trial. Pessoto 2010 excluded women with a record of “severe diseases”, breast malformation or reductive breast surgery. Steurer 2017 excluded women who were critically ill or/and had a history of breast surgery. Stutte 1998 excluded women with breast engorgement or a history of breast surgery.

Interventions

The interventions assessed by the 42 individually included studies contributing outcomes (data or narrative) to the review analyses, are described below with the studies organised in

the four breastmilk expression intervention types used to structure the analysis: pump versus hand expression; type of pump/pumping; instruction/education and support; and protocols relating to timing of expression and/or technique. The 10 new studies (not included in Becker 2016) are asterisked.

Pump versus hand expression (n = 14 studies)

- Two studies assessed any pump compared with hand expression (Boo 2001; Slusher 2007)
- Two studies assessed a manual pump versus hand expression (Paul 1996; Pessoto 2010; Slusher 2007)
- Six studies evaluated large electric pumping compared with hand expression (Flaherman 2012; Garza 1982; Lussier 2015; Mangel 2015; Pessoto 2010; Slusher 2007; Vasan 2004)
- One study (Steurer 2017*) evaluated hand expression before using the electric pump for the first 7 days post birth in mothers of premature infants.
- Four studies assessed expression using a pump with breast massage (i.e. combined with hands expression) versus without breast massage (Jones 2001; Mersmann 1993; Stellwagen 2010; Stutte 1988)

Type of pump/pumping (n = 13 studies, two of which reported outcomes for pump versus hand expression)

- One study evaluated a manual pump versus another manual pump (Barnabe-Garcia 2012)
- One study evaluated a manual pump versus small electric hand-held pump (Fewtrell 2001a)
- Three studies assessed a battery/small electric pump versus another battery/small electric pump (Francis 2008; Kennedy 2016*; Hopkinson 2009)
- Three studies assessed large electric pump versus manual pump (Slusher 2007; Fewtrell 2001b; Pessoto 2010)
- Two studies assessed a large electric pump versus battery/small electric pump (Burton 2013; Francis 2008)
- Two studies assessed simultaneous versus sequential pumping (Hill 1999;
- Two studies evaluated different sizes of pump breast shields (Prime 2010; Prime 2012)

Instruction/education and support (n =12 studies)

- Four studies assessed relaxation (for example listening to music, or foot massage) versus no specified relaxation technique (Feher 1989; Keith 2012; Lawrence 2016*; Mohammadpour 2018*)
- Three studies assessed one relaxation whilst compared to another relaxation technique (Demirci 2016*; Lawrence 2017*; Mirzaie 2018*)
- Five trials assessed instruction support versus no specific instruction (Ahmed 2008; Heon 2011; McLachlan 2016*; Niela-Vilen 2016*; Pinelli 2001)

- One trial assessed warming the breast versus no warming (Yigit 2012)

Protocols relating to timing of expression and/or technique (n = 5 studies)

- Two studies assessed one vacuum protocol compared to another vacuum protocol (Meir 2012; Zhang 2017*)
- Two studies evaluated different times of initiation of breastmilk expression (Parker 2012; Parker 2017)
- One study evaluated different frequencies of breast expression (De Carvalho 1985)

For additional details on the interventions assessed by the included studies, and other characteristic of the included studies, see appendix 4: Characteristics of included study tables.

Outcomes

For the primary outcomes, data in a format suitable for analysis were reported for quantity of milk expressed by 19 trials (Barnabe-Garcia 2012; Burton 2013; Feher 1989; Flaherman 2012; Francis 2008; Groh-Wargo 1995; Heon 2011; Hill 1989; Hopkinson 2009; Lussier 2015; Meier 2012; Mirzaie 2018; Mohammadpour 2018; Pessoto 2010; Pinelli 2001; Slusher 2007; Steurer 2017; Stutte 1988; Yigit 2012; Zhang 2017), quality of milk expressed six trials (Feher 1989; Garza 1982; Keith 2012; Mangel 2015; Pessoto 2010; Stutte 1988), and maternal satisfaction three trials (Mirzaie 2018; Steurer 2017; Zhang 2017).

Additionally for the primary narrative outcomes, narrative was reported for quantity of milk expressed by seven trials (Fewtrell 2001a; Kennedy 2016; Jones 2010; Lawrence 2016; Parker 2012; Prime 2010; Stellwagen 2010), quality of milk expressed by one trial (Stellwagen 2010) and maternal satisfaction by ten trials (Barnabe-Garcia 2012; De Carvalho 1985; Fewtrell 2001a; Fewtrell 2001b; Flaherman 2012; Heon 2011; Hopkinson 2009; Lawrence 2016; Meir 2012; Paul 1996).

No outcomes (narrative or data) were available for inclusion in the review synthesis for the following nine of the 51 included trials: Auerbach 1990; Boutte 1985; Costa 1999; Hayes 2008; Jayamala 2015; Meier 2008; Pittard 1991; Rasmussen 2001; Zinaman 1992.

For additional details on the outcome reported by the individual trials, including the range of secondary outcomes and measures, see Tables 2-4.

Funding

Funders of the included systematic review were: Department of Health Promotion, National University of Ireland, Galway; Cochrane (fellowship from the Health Research Board, Ireland); the Evidence and Programme Guidance Unit, Department of Nutrition for Health and Development (grant); WHO; and National Institute for Health Research (via Cochrane Infrastructure to Cochrane Pregnancy and Childbirth).

Considering the 10 included RCTs updating the Becker review, six (Demirci 2016; McLachlan 2016; Mirzaie 2018; Mohammadpour 2018; Steurer 2017; Zhang 2018) reported sources of funding. All the funders were either Governments, Universities or Hospitals. Funding was not reported by the authors of the remaining four included RCTs (Kennedy 2016; Lawrence 2017; Parker 2017; McLachlan 2016).

Author declarations of interest

All the authors of the Becker 2016 systematic review declared no conflicts of interest. Additionally, all authors of the ten included RCTs (Demirci 2016; Kennedy 2016; Lawrence 2017; Mirzaie 2018; Niela-Vilen 2016; McLachlan 2016; Mohammadpour 2018; Parker 2017; Steurer 2017; Zhang 2018) declared no conflicts of interest.

Excluded articles

A total of 57 studies were excluded during the screening of full text articles. Most of the articles excluded during full text examination reported RCTs that assessed breastfeeding education and support interventions and were excluded because they either clearly did not include a breastmilk education/support component, or may have but it was unclear, as they did not **clearly specify it, or** report results from such a component separately (refer to appendix 5 for the list of excluded articles and reasons).

Ongoing and awaiting classification studies

Two articles reporting two study protocols were assessed as ongoing, and two articles reporting two studies were as awaiting classification (see appendix 6 for further details).

3.2 Risk of bias

Included systematic review

We assessed the included systematic review as low risk of bias overall. However, we assessed the domain judging the appropriateness of the interpretation of the evidence as unclear risk of bias due to the concern that some conclusions are drawn about potentially effective and acceptable interventions when certainty is not warranted by the nature of the evidence synthesized in the review (only one study with small to moderate numbers of participants included in analysis, for all except one comparison and outcome, for which only two small studies were included). (see Appendix 4 for the assessments of the different risk of bias domains).

Included RCTs updating the Becker 2016 review

Allocation (selection bias)

With respect to random sequence, five trials were considered low risk given they described computer generated permuted blocks, sequences or randomised tables as used for allocation (Demirci 2016; Mirzaie 2018; Niela-Vilen 2016; Steurer 2017; Zhang 2017). The other five trials (Kennedy 2016; Lawrence 2017; McLachlan 2016; Mohammadpour 2018; Parker 2017) were classified as unclear risk as they failed to give enough detail about allocation.

Considering adequacy of blinding during randomisation, five studies were considered low risk (McLachlan 2016; Mirzaie 2018; Niela-Vilen 2016; Zhang 2017) as they described that sealed envelopes were given to participants. For the remaining five trials (Demirci 2016; Kennedy 2016; Lawrence 2017; Mohammadpour 2018; Parker 2017), the risk of selection bias due to lack of allocation concealment was judged to be unclear, with no methods detailed, or the reported methods lacking insufficient detail.

Blinding of participants and personnel

Mirzaie 2018 stated that while complete blinding was not possible, both participants and personnel were blinded to the intervention. Kennedy 2016 stated researchers sat with their backs to the participants, whilst Parker 2017 did not give enough information as the

information was by way of a published conference paper. As a result, these studies were rated as unclear.

The other seven studies (Demirci 2016; Kennedy 2016; MacLachlan 2016; Mohammadpour 2018; Niela-Vilen 2016; Steuer 2017; Zhang 2017) were assessed as high risk. This was because, given the nature of the intervention, blinding of the participants and personnel was unfeasible.

Blinding of outcome assessors

Five studies (Kennedy 2016; Lawrence 2017; Mirzaie 2018; Parker 2017; Zhang 2017) were classified as unclear risk for risk of bias. Blinding of the outcome assessors was not reported in each of the published papers. The other five other trials (Demirci 2016; McLachlan 2016; Mohammadpour 2018; Steuer 2017; Zhang 2017) were rated as high risk. Four out of the five trials in this category reported no blinding but Zhang (2017) did state that although researchers were blinded **to assessing the analogue and maternal fatigue assessments** of their study, they were not blinded to the other assessments in their trial.

Incomplete outcome data (attrition bias)

Two trials (Demirci 2016 & Mohammadpour 2018) were assessed as low risk. Six trials (Kennedy 2016; Lawrence 2017; Mirzaie 2018; Parker 2017; Steuer (2017); Zhang (2017) were judged at unclear risk of attrition bias, either because the information provided was insufficient to confidently assess the risk as high or low, or because there was some attrition, but the level was small and relatively even across the groups, making it difficult to assess the implication for bias. Two trials, McLachlan 2016 and NielaVilen 2016, were rated high risk due to high level and uneven distribution of attrition.

Selective reporting

Three trials were judged low risk of selective reporting (McLachlan 2016; Mirzaie 2018; Steuer 2017) as all outcomes specified in the protocols for these trials were reported, even if for some of the trials, the range of outcomes reported was limited. Four trials (Demirci 2016; Mohammadpour 2018; Lawrence 2017; Zhang 2017) were deemed as unclear risk due to inability to access the protocols to check the reported outcomes against those specified in the protocol. Two of these trials identified a trial registration number, however the author was unable to access the protocols. Three trials (Kennedy 2016; Parker 2017; Niela-Vilen 2016) were assessed high risk of selection bias. Kennedy 2016 had missing outcomes data in the conference abstract report and no accessible protocol; Parker 2017 had missing outcomes data and missing specified outcomes (no reporting of time taken to lactogenesis II although specified in the abstract); the Niela-Vilen 2016 study had missing outcomes data (means and SDs).

Other bias

Niela-Vilen 2016 was assessed as low risk of other bias given characteristics of participants were similar and there were no other signs of bias. Six of the included RCTs were assessed as unclear risk of other bias due to lack of information on methods precluding assessment or concern about the potential of small sample to prevent determination of intervention effect (Kennedy 2016; Lawrence 2017; Mirzaie 2018; Mohammadpour 2018; Parker 2017; Steuer 2017). Three studies were judged as high risk of other bias: Demirci 2016 for concern about potential differences across groups at baseline; and McLachlan 2016 and Zhang 2017 for intervention infidelity.

Figure 2: Review authors' judgements about each risk of bias item presented as percentages across new RCTs (n=10)

Random sequence generation (selection bias)	50%		50%	
Allocation concealment (selection bias)	50%		50%	
Blinding: participants and personnel (performance bias)	30%	70%		
Blinding: outcome assessment (detection bias)	50%		50%	
Incomplete outcome data (attrition bias)	20%	60%		20%
Selective reporting (reporting bias)	30%		40%	30%
Other bias	10%	60%		30%

Low risk of bias



Unclear risk of bias



High risk of bias



Figure 3: Review authors' judgements about risk of bias items for each included study

Systematic review *							
	Study eligibility criteria	Identification and selection of studies	Data collection and study appraisal	Synthesis and findings	Interpretation	Overall risk of bias	
Becker 2016							
RCTs **							
	Random sequence generation	Allocation concealment	Blinding of participants & personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Demirci 2016							
Kennedy 2016							
Lawrence 2017							
McLachlan 2016							
Mirzaie 2018							
Mohammadpour 2018							
Niela-Vilen 2016							
Parker 2017							
Steuere 2017							
Zhang 2017							

Note: * ROBIS tool used to assess included systematic review (see Whiting 2016 for the tool), ** Cochrane RCT risk of bias assessment tool in the Cochrane Handbook and ReVMan statistical package used to assess the RCTs.

3.3 Intervention effects and acceptability

PUMP versus HAND EXPRESSION

The results of the synthesis for the five pump versus hand expression comparisons are shown in Table 2 (*analysis 1 – 5*), together with the narrative outcomes for these comparisons.

Differences observed between groups in outcome measures, and which group was favoured, are in bold text.

Table 2: Pump versus hand expression comparison results

STUDY (n)	OUTCOME	#/MD [SD]	RR or MD (95% CI)
Analysis 1: Any pump versus hand expression			
Boo 2001 N=28 (15/13)	Adverse effects; ≥1 contaminated milk sample	13/15 vs 10/13	1.13 (0.79 to 1.61)
	Transfer to feeding at breast	6/15 vs 7/13	1.30 (0.63 to 2.67)
Narrative: <u>Acceptability (maternal satisfaction)</u> – Slusher 2007, comparing hand expression to expression using an electric pump and pedal-operated pump, reported experiencing the pump as uncomfortable as a reason for some women dropping out of the trial.			
Analysis 2: Manual pump versus hand expression			
	<u>Quantity of milk expressed</u>		
Pessoto 2010 N=28 (15/13)	Volume of milk expressed day 4-5	224.4 [205] vs 146.46 [167]	73.94 mls (-64.11 to 211.99)
Slusher 2007 N=48 (29/19)	Volume of milk over 6 days pumping	631.7 [426] vs 419.6 [290]	212.10 mls (9.39 to 414.8) (favours manual pump)
	<u>Quality of milk expressed</u>		
Pessoto 2010 N=118 (64/54)*	Potassium concentration	15.2 [3.3] vs 14 [3.1]	1.20 mmol/L (0.04 to 2.36)
Pessoto 2010 N=141 (80/61)*	Energy content	630.5 [170] vs 601.7 [106]	28.20 kcal/L (-16.94 to 74.54)
Pessoto 2010 N=118 (64/54)*	Sodium concentration	25 [8.1] vs 31 [12.1]	-6.00 mmol/L (-9.79 to - 2.21) (favours hand expression)
Pessoto 2010 N=118 (64/54)*	Protein concentration	10.8 [3.7] vs 12.1 [3.3]	-1.30 g/L (-2.56 to -0.04) (favours hand expression)
Pessoto 2010 N=142 (80/62)*	Adverse effects; bacterial level (Dornic degrees of acidity)	1.9 [1.2] vs 1.7 [1.1]	0.20 (-0.18 to 0.58)
Narrative: <u>Acceptability (maternal satisfaction)</u> – Paul 1996 reported that some women preferred the manual pump, others hand expression; <u>Adverse events (mother nipple damage)</u> – Pessoto 2010 reported one women in manual pump group, none in hand expression group.			
Analysis 3: Large electric pump versus hand expression			
	<u>Maternal satisfaction</u>		
Flaherman 2012 N=68 (33/35)	Breastfeeding Self- Efficacy Scale (1-5 scale)	3 [1.2] vs 2.3 [1.1]	0.70 (0.15 to 1.25) (favours hand expression)
	Breast Milk Expression Experience (1-5 scale)	4.1 [0.9] vs 4.5 [0.5]	-0.40 (-0.75 to -0.05) (favours hand expression)
	<u>Quantity of milk expressed</u>		
Slusher 2007 N=43 (24/19)	Mean volume over 6 days	792.7 [418] vs 419.6 [290]	373.1 mls (161.1 to 585.1) (favours large electric pump)
Flaherman 2012 N=68 (33/35)	Volume for 1 expression	2.9 [7.7] vs 0.8 [1.4]	2.10 mls (-0.57 to 4.77)

	12-36 hours postpartum		
Lussier 2015 N=26 (14/12)	Volume over day Day 1 Day 2 Day 3 Day 4	17.12 [29.23] vs 3.2 [5.63] 19.9 [27.49] vs 4.25 [5.24] 69.86 [85.8] vs 18.6 [17.2] 182 [136] vs 81 [72]	13.92 mls (-1.72 to 29.56) 15.65 mls (0.95 to 30.35) (favours large electric pump) 51.11 mls (5.12 to 97.10) (favours large electric pump) 100.5 mls (18.33 to 182.67) (favours large electric pump)
Lussier 2015 N=26 (14/12); Pessoto 2010 N=25 (12/13)	Day 5	Trials Pooled	128.25 mls (30.64 to 225.87) (favours large electric pump)
Lussier 2015 N=26 (14/12)	Day 6 Day 7	298.4 [211.8] vs 173.6 [171] 320.2 [256] vs 195.3 [207.6]	124.87 mls (-22.09 to 271.8) 124.9 mls (-53.37 to 303.17)
	<u>Quality of milk expressed</u>		
Pessoto 2010 N=111 (57/54)*	Protein concentration	12.2 [3.7] vs 12.1 [3.3]	0.10 g/L (-1.20 to 1.40)
Mangel 2015 N=21		N/A inverse variance	0.19 g/L (-0.92 to 1.30)
Pessoto 2010 N=111 (57/54)*	Potassium concentration	15 [32] vs 14 [3.1]	1.00 mmol/L (-0.17 to 2.17)
	Sodium concentration	24.1 [6.8] vs 31 [12.1]	-6.90 mmol/L (-6.9 to -3.2) (favours hand expression)
Pessoto 2010 N=111 (57/54)*	Energy content	590.1 [130.2] vs 601.7 [106]	-11.60 kcal/L (-53.73 to 30.53)
Mangel 2015 N=21	Protein	N/A, inverse variance	0.19 g/L (-0.92 to 1.30)
	Energy	N/A, inverse variance	45.71 kcal/L (-3.34 to 94.8)
	Carbohydrate	NA, inverse variance	0.05 g/L (-0.99 to 1.08)
	Fat	NA, inverse variance	3.10 g/L (-2.22 to 8.41)
Garza 1982 N=36 (18/18)	Total nitrogen	220 [20] vs 210 [20]	10.00 mg/dL (-3.07 to 23.07)
	<u>Adverse effects</u>		
Flaherman 2012 N=68 (33/35)	Maternal breast pain (scale 1-10)	0.73 [1.5] vs 0.71 [1.4]	0.02 (-0.67 to 0.71)
Pessoto 2010 N=123 (61/62)*	Bacterial level in milk (Dornic degrees of acidity)	1.81 [1.1] vs 1.7 [1.1]	0.10 (-0.29 to 0.49)
Narrative: <u>transfer to feeding at the breast</u> – Vasan 2004 reported that women assigned to hand-expression had greater milk transfer on the day of hospital discharge than women assigned to the electric pump.			
<i>Analysis 4: Hand expression for 7 days versus 3 days, prior to electric pump use (analysis 4)</i>			
Steurer 2017 N=34 (16/18)	<u>Quantity of milk expressed: volume on 14th day postnatal</u>	700 [550] vs 582 [331.2]	117.30 mL (-192.60 to 427.20)
	Maternal acceptability:	76.5 [14.7] vs 80.3 [9.3]	-3.10 (12.19 to 4.59)

	breastfeeding self-efficacy scale for mothers of ill and/or preterm infants (BSES-SF) (scale with 18 items, possible score of 1-5 for each, higher better)		
Analysis 5: Breast massage versus no breast massage			
Stutte 1988 N=36	Quantity of milk expressed 2 expressions	N/A inverse variance	4.82 mls (1.25 to 8.39) (favours breast massage)
	Quality of milk expressed: fat content (crematocrit %)	N/A inverse variance	1.92 (1.02 to 2.82) (favours breast massage)
Narrative: <u>quantity of milk expressed</u> – two trials, Jones 2001 and Stellwagen 2010, reported a higher quantity with breast massage compared with without breast massage.			
Narrative: <u>quality of milk expressed</u> (protein, caloric and carbohydrate content) – Stellwagen 2010 reported that the milk protein content of milk from women who combined hand expression with expression using a pump was lower than that in milk from women who expressed using the pump only, however the carbohydrate content was higher in the breast massage group, and there was no evidence of a difference between groups in caloric content of expressed milk.			
Narrative: <u>maternal physiological effects of expressing or pumping</u> (oxytocin release) – Mersmann 1993 reported that more mothers in the breast massage group experienced milk leaking (oxytocin release) than women in the no breast massage group.			

Abbreviations: MD: mean difference; RR: risk ratio; SD: standard deviation

Notes: *assumed to be multiple measures

TYPE of PUMP/PUMPING

The results of the review synthesis for the seven comparisons relating to type of pump/pumping are shown in Table 3 (*analysis 6-12*). Bold text indicates difference between groups and which group was favoured.

Table 3: Pump/pumping comparison results

STUDY (n)	OUTCOME	#/MD [SD]/comparison	RR or MD (95% CI)
<i>Analysis 6: Manual pump versus another manual pump</i>			
Bernabe-Garcia 2012 N=32 (crossover study)	Quantity of milk expressed over 24 hours	Isis vs Harmony	4.57 ml (-13.42 to 22.56)
		Isis vs Little Heart	15.02 ml (-13.32 to 43.36)
		Isis vs Evenflo	30.49 ml (3.40 to 57.58) (favours Isis)
		Harmony vs Little Heart	12.13 ml (-9.68 to 33.94)
		Harmony vs Evenflo	28.50 ml (12.11 to 44.89) (favours Harmony)
		Little Heart vs Evenflo	15.47 ml (-75.3 to 106.2)
Narrative: <u>Acceptability (time taken to express)</u> – Bernabe-Garcia 2012 reported no difference between any of the manual pump groups compared.			
<i>Analysis 7: Manual pump versus small electric hand-held pump</i>			

<p>Narrative: <u>quantity of milk expressed</u> – Fewtrell 2001a reported observing no difference between women of eight-week-old term infants who expressed using any manual pump (Avent Isis) compared with the small electric pump (Medela) in total amount expressed over 20 minute-test sessions;</p> <p><u>acceptability (maternal satisfaction)</u> – Fewtrell 2001a also reported that mothers were more satisfied with the manual pump compared to the electric pump for comfort (73% versus 20%), pleasant to use (58% versus 20%) and overall qualities (69% versus 42%), however observing no difference between the groups for ease of use (63% versus 65%) and amount of suction (67% versus 71%). Women in this trial were given a choice of which pump to keep; 64% selected the manual pump, 34% the small electric pump and two neither.</p>			
Analysis 8: Type of battery/small electric pump (analysis 7)			
Francis 2008 N=40 (20/20)	Volume of milk (one expression)	80 [48] vs 65 [23] (small electric Swing/ small electric UNO)	15.00 ml (-8.33 to 38.33)
Hopkinson 2009 N=59 (29/30)	Change in 24-hour milk production	205 [257] vs 143 [151] (small electric Medela/ small electric Playtex)	62 g (-46.02 to 170.02)
Francis 2008 N=40 (20/20)	Time taken to express	18 [5] vs 14 [4] (small electric Swing/ small electric UNO)	4.00 minutes (1.19 to 6.81) (favours UNO)
	Time to milk ejection	94 [52] vs 87 [38]	7.00 seconds (-21.2 to 35.2)
<p>Narrative: <u>Quantity of milk expressed</u> (milk weight, g) – Kennedy 2016, in comparing the Philips AVENT Comfort + Natural/Medela Swing + Calma pump) reported “Did not differ”; <u>Acceptability (maternal satisfaction)</u> – Hopkinson 2009 reported that mothers ratings of the pumps compared did not differ on eight of ten items compared.</p>			
Analysis 9: Large electric versus manual pump			
	<u>Quantity milk expressed</u>		
Slusher 2007 N=53 (24/29)	Volume over 6 days pumping	792.7 [417.5] vs 631.7 [426]	161 ml (-66.90 to 388.90)
Fewtrell 2001b N=145 (71/74)	Volume per day pumped	240.72 [165.98] vs 235.65 [211.01]	5.07 ml (-56.59 to 66.73)
Pessoto 2010 N=27 (12/15)	Volume expressed on day 5	373.08 [476.14] vs 222.4 [205.12]	150.68 ml (-138.02 to 439.38)
Fewtrell 2001b N=145 (71/74)	<u>Time taken to express</u>	53.26 [22.56] vs 73.53 [26.68]	-20.27 minutes (-28.30 to -12.24) (favours electric pump)
	Time spent pumping/day		
Pessoto 2010 N=121 (57/64)*	Sodium concentration	24.1 [6.8] vs 25 [8.1]	-0.90 mmol/L (-3.56 to 1.76)
	Potassium concentration	15 [3.2] vs 15.2 [3.3]	-0.20 mmol/L (-1.36 to 0.96)
	Protein content	12.2 [3.7] vs 10.8 [3.7]	1.40 g/L (0.08 to 2.72) (favours electric pump)
Pessoto 2010 N=141 (61/80)*	Energy content	590.1 [130.2] vs 630.5 [169.8]	-40.40 kcal/L (-89.92 to 9.12)
	Bacterial level (Dornic degrees of acidity)	1.8 [1] vs 1.9 [1.2]	-0.10 (-0.46 to 0.26)
<p>Narrative: <u>Acceptability (maternal satisfaction)</u> – Fewtrell 2001b reported that women rated the manual pump (Avent Isis) better than the large electric pump (Egnell/Ameda) for all items including ease of use (P=0.03), comfort (P=0.003), pleasant to use (P=0.01), overall opinion (0.003), and amount of suction (P = 0.05). Boutte 1985 reported that women were equally satisfied with the manual and large electric pump on all items except ease of operation, for which the manual pump was rated more better. <u>Adverse effects (mother)</u> – The same trial reported similar proportions of women in the large electric and manual pump groups with sore nipples (7% both groups) and engorgement (4% in manual pump group vs 6% in electric pump group).</p>			
Analysis 10: Large electric pump versus battery/small electric pump			
	<u>Quantity of milk expressed</u>		

Francis 2008 N=40 (20/20)	One expression	85 [36] vs 65 [23] Whittlestone/UNO pump 85 [36] vs 80 [48] Whittlestone/Swing pump	20.00 mls (1.28 to 38.72) (favours large electric) 5.00 mls (-21.30 to 31.30)
Burton 2013 N=62 (29/33)	Expression over one day	221 [156] vs 229 [181]	-8.00 g (-91.89 to 75.89)
Burton 2013 N=58 (27/31)	Milk weight from 15 min simultaneous pumping	80 [44.1] vs 57.2 [50.2]	22.80 g (-1.47 to 47.07)
Time taken to express			
Burton 2013 N=61 (29/32)	Each day	75 [37] vs 82 [32] Symphony/Avent Twin	-7.00 minutes (-24.34 to 10.34)
Francis 2008 N=40 (20/20)	One expression	12 [4] vs 18 [5] Whittlestone/UNO pump 12 [4] vs 14 [4] Whittlestone/Swing pump	-6.00 minutes (-8.81 to -3.19) (favours large electric pump) -2.00 minutes (-4.48 to 0.48)
Francis 2008 N=40 (20/20)	Time to milk ejection	68 [39] vs 94 [52] UNO pump 68 [39] vs 87 [38]	-26.00 seconds (-54.49 to 2.49) -19.00 seconds (-42.86 to 4.86)
Narrative: <u>Acceptability (maternal satisfaction)</u> – Burton 2013 reported some women preferred the small electric pump compared with the large electric pump due to ease of use (including the positioning of the button); <u>Breastfeeding at discharge</u> – Burton 2013 observed that infants of mothers who used the small electric pump were more likely to be breastfeeding at NICU discharge than women who used the large electric pump.			
Analysis 11: Simultaneous versus sequential pumping			
Quantity of milk expressed			
Hill 1999 N=49 (23/26)	Total over weeks 2-5	15,404.89 [10,427.16] vs 11,105.95 [8,439.98]	4298.94 g (-1056.80 to 9654.68)
Groh-Wargo 1995 N=32 (16/16)	Total mls per week	2,787 [1939] vs 2685 [2016]	102.00 mls (-1268.57 to 1472.57)
Groh-Wargo 1995 N=32 (16/16)	Time taken to express; Hours per week	7.6 [3] vs 11.1 [3.1]	-3.50 hours (-5.61 to -1.39) (favours simultaneous)
	Maternal physiological effects; serum prolactin change	7.7 [7.6] vs 11.4 [11.9]	-3.70 fold increase (-10.62 to 3.22)
Analysis 12: Large versus small breast shield			
Narrative: <u>Quantity of milk expressed</u> – Prime 2010 reported observing a greater milk output in women who used a breast shield size of >24 mm when pumping, compared with a breast shield size of ≤ 24mm; <u>Maternal physiological effects</u> – Prime 2010 and Prime 2012 reported observing no difference in time to first milk flow between groups of women who used different sizes of breast shields attached to pumps.			

Abbreviations: MD: mean difference; NICU: neonatal intensive care unit; RR: risk ratio; SD: standard deviation

Notes: *assumed to be multiple measures

INTRUCTION/EDUCATION and SUPPORT

Table 4 presents the results of the synthesis for the four instruction/education and support comparisons (analysis 13 – 16, bold text indicates difference observed between groups, and which intervention was favoured)

Table 4: Instruction/education and other support comparison results

STUDY (n)	OUTCOME	#/MD [SD]/comparison	RR or MD (95% CI)
<i>Analysis 13: Relaxation technique versus no relaxation technique</i>			
	<u>Quantity of milk expressed</u>		
Feher 1989 N=55 (30/25) Keith 2012 N=160 (117/43)	Volume for one expression	90.1 [60] vs 55.4 [48.2]	34.70 mls (6.10 to 63.30)
	Day 1		17.00 mls (9.27 to 24.73)
	Day 5	39.6 [29.3] vs 22.6 [18.8]	85.10 mls (63.13 to 107.07)
	Day 10	177.2 [84.5] vs 92.1 [52.7]	277.40 mls (207.75 to 347.05)
	Day 14	511.3 [267.9] vs 233.9 [167.1] 821.5 [388.7] vs 318.2 [200.8]	503.40 mls (410.76 to 595.84) (favours relaxation)
Mohammadpour 2018 N=56 (28/28)	Change in volume/day, assessed on day 7 (last day of intervention)	20.98 [6.99] vs 18.74 [7.5]	2.24 cc (-1.78 to 6.26)
Keith 2012 N=160 (117/43)	Fat content on day 1	49.3 [13.7] vs 40.7 [14.3]	8.60 g/L/day (3.66 to 13.54)
	Fat content on day 5	55.1 [31.9] vs 43.1 [12.2]	12.00 g/L/day (5.17 to 18.83)
	Fat content on day 10	61.4 [61] vs 47.4 [13.3]	14.00 g/L/day (2.25 to 25.75)
	Fat content on day 14	68.3 [4.72] vs 46.6 [12.5]	21.70 g/L/day (17.87 to 25.53) (favours relaxation)
Feher 1989 N=55 (30/25)	Creamatocrit % (one sample)	7.2 [2.9] vs 6.8 [2.4]	0.40 (-1.00 to 1.80)
Narrative: <u>Quantity of milk expressed</u> – Lawrence 2016 (n = 33, cross over study) reported that evaluation of 186 pumping sessions, showed difference in volume of milk produced per expression when mothers expressed whilst listening to harp music, music of choice, and no music (62 sessions assessed for each group); <u>Acceptability (maternal satisfaction)</u> – Fehr 1989 reported mothers were positive about their experiences of listening to music while expressing; Lawrence 2016 reported mothers preferred “some background music rather than silence” during milk expression.			
<i>Analysis 14: Relaxation technique versus another relaxation technique</i>			
	<u>Quantity of milk expressed</u>		
Mirzaie 2018 N=74 (37/37) (foot massage focused on milk production points/general foot massage)	Change in volume of first breast milk expressed after massage, assessed on day 7 (last day of intervention)	8.6 [9.0] vs 1.0 [3.8]	7.60 ml (4.45 to 10.75) (favours foot reflexology focused on milk production points)

	Change in volume/ day, assessed on day 7	58.0 [64.6] vs 8.9 [47.9]	49.10 ml (23.19 to 75.01) (favours foot reflexology focused on milk production points)
Mirzaie 2018 N=74 (37/37)	Maternal satisfaction: very satisfied or satisfied (self-report)	20/37 vs 12/37	1.67 (0.96 to 2.89)
	Breastfeeding (exclusive), assessed on day 7, end of intervention	5/37 vs 1/37	5.00 (0.61 to 40.75)
	Change in infant weight over 7-day intervention period	193.5 [124.7] vs 150.7 [92.7]	42.80 g (-7.27 to 92.87)
	Maternal depression; DASS-21 scale, day 7 (end of intervention)	4 [4.5] vs 3.8 [4.2]	0.20 (-1.78 to 2.18)
	Maternal anxiety; DASS-21 scale, day 7 (end of intervention)	4 [3.8] vs 3.8 [4]	0.20 (-1.58 to 1.98)
	Maternal stress; DASS-21 scale, day 7 (end of intervention)	7.7 [4.7] vs 7.6 [4.2]	0.10 (-1.93 to 2.13)
Demirci 2016 N=11	Breastfeeding (any) at 2 months	3/5 vs 3/6	1.20 (0.41 to 3.51)
Narrative: <u>Quantity of milk expressed</u> – Lawrence 2017 (n = 33, cross over study) reported that evaluation of 186 pumping sessions, showed difference in volume of milk produced per expression when mothers expressed whilst listening to harp music, music of choice, and no music (62 sessions assessed for each group)			
<i>Analysis 15: Instruction support versus no specific instruction</i>			
	<u>Quantity of milk expressed</u>		
Pinelli 2001 N=128 (64/64) Heon 2011 N=33 (14/19)	Volume/time (in NICU)	72 [65] vs 66 [64]	6.00 mls (-16.35 to 28.35)
	Volume/day, week 1	237.56 [124.56] vs vs 308.69 [219.81]	-71.13 mls (-189.56 to 47.30) -38.89 mls (-261.49 to 183.71)
	Volume/day, week 2	536.81 [299.81] vs 575.7 [350.86]	-51.00 mls (-198.00 to 300.00) 42.69 mls (-222.22 to 307.60)
	Volume/day, week 3	646.6 [361.68] vs 595.6 [359.35]	47.38 mls (-252.82 to 347.58) 42.47 mls (-274.99 to 359.93)
	Volume/day, week 4	670.73 [384.09] vs 628.04 [383.27]	
	Volume/day, week 5	705.57 [436.48] vs 658.19 [432.63]	
	Volume/day, week 6	672.16 [[488.97] vs 629.69 [417.12]	
Heon 2011 N=33 (14/19)	<u>Time taken to express</u> Minutes/day, week 1	112.1 [31.2] vs	1.16 mins (-14.34 to 29.74)

	Minutes/day, week 2	104.4 [32.9] 117.7 [26.3] vs 105.4 [29.3]	12.30 mins (-6.76 to 31.36)
	Minutes/day, week 3	119.7 [36.8] vs 96.7 [35.9]	23.00 mins (-2.14 to 48.14)
	Minutes/day, week 4	126.7 [35.8 vs 95.4 [34]	31.30 mins (7.11 to 55.49)
	Minutes/day, week 5	123.1 [35.3] vs 95.1 [32.8]	28.00 mins (4.35 to 51.65)
	Minutes/day, week 6	128.3 [41.7] vs 92.7 [40]	35.60 mins (7.30 to 63.90) (favours support)
Ahmed 2008 N=60 (30/30)	Transfer to feeding at breast	24/30 vs 12/30	2.00 (1.25 to 3.21) (favours support)
McLachlan 2016 Cluster RCT	Breastfeeding (any) at 4 months		
Home visits compared with standard care N = 1513 (735/778)*	Home visits compared with standard care	461/735 vs 419/778	1.16 (1.07 to 1.27) (favours home visits compared with standard care)
Home visits + drop-in centre compared with standard care N = 1533 (755/778)*	Home visits + drop- in centre compared with standard care	411/755 vs 419/778	1.01 (0.92 to 1.11)
Narrative: <u>acceptability (maternal satisfaction)</u> - Heon 2011, evaluating a multi-component support protocol to assist women to express milk, reported that most women strongly agreed or agreed that various components were beneficial for the establishment and maintenance of their milk production including the education session (11/14) and telephone follow-up (10/12).			
Narrative: <u>breast milk expression initiation</u> - Ahmed 2008 reported that mothers who received an educational programme were more likely to start milk expression earlier compared to mothers who received no specific instruction (P<0.004).			
Narrative: <u>breastmilk expression duration</u> - Niela-Vilen 2016 reported that the median duration of breast milk expression in women who received breastfeeding education and support (including advice about how to express) (n=31) was 4.0 months (1.5-11.0 months), compared with a mean length of 3.8 months (0-5-9.0) for women who received no specific instruction (n=30).			
Narrative: <u>breast feeding at 3 months (any and exclusive)</u> - Niela-Vilen 2016 reported a median duration of any breastfeeding in the instruction group (n = 47) of 3 months, and of 4.2 months in the no instruction group (n=48) (ranges 0-14 and 0-13 months for the groups respectively). The same study reported no women in either group exclusively breastfeeding.			
<i>Analysis 16: Warming the breast versus no warming</i>			
	<u>Quantity of milk expressed</u>		
Yigit 2012 N=78 (39/39)	Expression 1	30.28 [25.04] vs 20.64 [20.42]	9.64 mls (-0.50 to 19.78)
	Expression 2	28.07 [20.76] vs 16.89 [15.75]	11.18 mls (3.00 to 19.36) (favours warming)
	Expression 3	44.1 [32.46] vs 33 [28.59]	11.10 mls (-2.48 to 24.68)
	Expression 4	39.69 [25.45] vs 27.3 [20.2]	12.39 mls (2.19 to 22.59) (favours warming)
	Expression 5	47.02 [23.01] vs 33.15 [19.98]	13.87 mls (4.31 to 23.43) (favours warming)
	Expression 6	45.07 [21.75] vs 32.05 [19.68]	13.02 mls (3.81 to 22.23) (favours warming)

Abbreviations: **MD:** mean difference; **NICU:** neonatal intensive care unit; **RR:** risk ratio; **SD:** standard deviation

Notes: * sample and group sizes adjusted for correlation between women in clusters; ** results from the Niela-Vilen 2016 trial were included as narrative as non-normal distribution of data precluded valid determination of means and standard deviations from the reported median and inter-quartile ranges.

PROTOCOLS relating to TIMING of EXPRESSION or TECHNIQUE

The results for the comparisons of different protocols relating to timing of expression or technique, are presented in Table 5 (analysis 17-19; bold text notes difference observed between the groups and which intervention was favoured).

Table 5: Technique and timing of expression comparison results

STUDY (n)	OUTCOME	#/MD [SD]/comparison	RR or MD (95% CI)
<i>Analysis 17: Any vacuum protocol versus another vacuum protocol</i>			
	<u>Quantity of milk expressed</u>		
*Meir 2012 N=67 (33/34) EXP initiation- EXP maintenance vs EXP initiation – STD	Total over day		
	Day 1	10.4 [15.8] vs 11.2 [16.2]	-8.0 ml (-8.46 to 686)
	Day 5	325.2[220.6] vs 445.8 [323.2]	-120.60 ml (-252.76 to 11.56)
	Day 14	483.9 [391.5] vs 622.1 [474.2]	- 138.20 ml (-346.19 to 69.79)
*Meir 2012 N=71 (33/38) EXP initiation - EXP maintenance vs STD-STD	Total over day		
	Day 1	10.4 [15.8] vs 13.2 [28.1]	-2.80 ml (-13.23 to 7.63)
	Day 5	325.2 [220.6] vs 312.4 [248.3]	12.80 ml (-96.28 to 121.88)
	Day 14	483.9 [391.5] vs 433.9 [333.6]	50.00 ml (-120.56 to 220.56)
*Meir 2012 N=72 (34/38) EXP initiation - STD vs STD- STD	Total over day		
	Day 1	11.2 [16.2] vs 13.2 [28.1]	-2.00 ml (-12.46 to 8.46)
	Day 5	445.8 [323.2] vs 312.4 [248.3]	133.40 ml (-0.89 to 267.69)
	Day 14	622.1 [474.3] vs 433.9 [333.6]	188.20 ml (-3.29 to 379.69)
Zhang 2017 N=98 (50/48) high pump pressure (- 150mmHg) compared with lower pump pressure (- 100mmHg)	8-hour (8:00 am to 4:00 pm) daytime output, day 4 after birth	164.28 [69.14] vs 102.6 [40.99]	61.68 g (39.28 to 84.08) (favours higher vacuum pump pressure)
	<u>Maternal satisfaction</u>		
Zhang 2017 N=98 (50/48)	Chinese version of the H&H lactation scale (20 items, higher better): at discharge 1 month after delivery	130.51 [12.97] vs 125.29 [13.51]	5.09 (0.01 to 10.17)

		133.90 (20.33) vs 120.35 (29.33)	13.55 (3.52 to 23.58) (favours higher vacuum pump pressure)
	<u>Adverse effects</u>		
Zhang 2017 N=98 (50/48)	Mother cracked nipples	33/50 vs 30/48	1.06 (0.79 to 1.42)
	Visual analogue pain scale (0-10, lower is better)	1.27 [0.83] vs 0.86 [1.44]	0.41 (-0.06 to 0.88)
Zhang 2017 N=98 (50/48)	Breastfeeding (exclusive): at discharge at infant age one month	28/50 vs 23/48 33/50 vs 24/48	1.11 (0.78 to 1.56) 1.32 (0.93 to 1.87)
	Maternal health (depression): Edinburgh Postnatal depression scale (0-10; higher is worse), 1 month after birth	1.45 [2.16] vs 1.33 [1.62]	01.2 (-0.63 to 0.87)
Narrative: <u>acceptability (maternal satisfaction)</u> - Meier 2012 reported that some mothers did not like the 'suction strength' of the experimental maintenance BPSP.			
<i>Analysis 18: Time of initiation of breast milk expression</i>			
<i>within 1 hour versus 1-6 hours of delivery</i>			
Narrative: <u>quantity of milk expressed</u> - Parker 2012 observed that expressing within 60 minutes of birth of a very low birthweight infant obtained higher mean milk quantity over the first week than initiating pumping 1-6 hours after delivery (mean group total of all milk volume days one to seven, 1374.7 ml versus 608.1 mL, P=0.05, n=20 Parker 2012); <u>maternal physiological effects</u> : - Parker 2012 reported that the time to lactogenesis stage II (mean hours) was lower for women who initiated expression within one hour of delivery compared with 1-6 hours of delivery (mean 80.4 hours versus 136.8, SD not reported).			
<i>within 1 hour versus 1-3 hours of delivery</i>			
Narrative: <u>Breastmilk feeding (lactation at 3 weeks, 6 weeks and discharge)</u> - Parker 2017 reported that mothers who initiated expression within 1-3 hours of delivery were more likely to be lactating at 3 weeks (88%), 6 weeks (63%) and at discharge (62%) compared to those who initiated expression within 1 hour (68%, 60%, 33%); the same study reported that mothers who expressed within 1-3 hours after birth had an earlier onset of lactogenesis stage II than mothers who initiated expression within 1 hour after birth.			
<i>within 1-3 hours versus 3-6 hours of delivery</i>			
Narrative: <u>Breastmilk feeding (lactation at 3 weeks, 6 weeks and discharge)</u> - Parker 2017 reported that mothers who initiated expression within 1-3 hours of delivery were more likely to be lactating at 3 weeks (88%), 6 weeks (63%) and at discharge (62%) compared to those who initiated expression within 3-6 hours following delivery (70%, 54% 35%); <u>maternal physiological effects</u> - Parker 2017 reported that mothers who initiated breast milk expression 1-3 hours following delivery had an earlier onset of lactogenesis stage II than mothers who initiated expression 3 to 6 hours after birth.			
<i>Analysis 19: Frequency of breast expression: ≥ 4 versus ≤3 times per day</i>			
Narrative: Quantity of milk expressed - De Carvalho 1985 (n = 25) reported that pumping four or more times per day resulted in a greater daily quantity of milk than pumping three or less times a day (mean 342, SD 229 mL versus 221, SD 141 mL, P > 0.02).			

Abbreviations: MD: mean difference; RR: risk ratio; SD: standard deviation

Note: * The interventions assessed in the Meier 2012 study (cross over trial), are poorly described. The description is as follows: standard breast pump suction pattern (BPSPs) (STD) consisted of an initial (two minute) stimulation phase of rapid (120 per minute) suction events that correspond to sucking at the breast prior to milk ejection under low milk flow conditions. experimental initiation BPSP (EXP -initiation) mimicked the rapid, irregular sucking rate and sucking rhythm used by healthy term infants during breastfeeding prior to lactogenesis II when only small amounts of milk are available for removal. The experimental maintenance BPSP (EXP-maintenance) started with a two-

minute stimulation phase identical to the standard. However, the expression phase of this pattern incorporated a different suction curve in which the rate varied as a function of the amount set by the mother (Meier 2012: 3).

Chapter 4: Discussion

4.1 Summary of main results

In this evidence review to assess the effects and acceptability of methods of breastmilk expression for lactating women and to inform guidelines and research priorities, we identified one Cochrane systematic review (Becker 2016) including 41 trials (last search date 21 March 2016) and 10 RCTs meeting the selection criteria, which we combined in a new synthesis, evaluated and interpreted. Overall, 10,134 mothers and their infants were involved in the 51 studies included in our review, with 42 of the trials contributing data or narrative outcomes. **The trials varied in size**, with the largest trial (the only cluster randomised controlled trial included) randomising 7039 women, and the smallest trial randomising 11 women. 9596 women and infants were randomised in the 42 trials that contributed to the synthesis. For the majority of trials that contributed data to the review analyses, far fewer women were included in the analyses than were randomised, with a maximum of 1533 women included in review analyses. Due to diversity across the included trials in the nature of the interventions assessed, and in outcome measures used, a large number of comparisons were assessed in separate analyses. Five of the nineteen reported comparisons were pump versus hand comparisons, seven pump/pumping comparisons, four instruction/education and support comparisons, and three were comparisons of timing of expression or pumping technique (different vacuum pressure whilst pumping).

Overall, data were included in analysis for 15 comparisons, and narrative outcomes were reported for four additional comparisons. Thirteen comparisons reported data for at least one primary outcome. Suitable data for inclusion in the review analysis was provided by three, six and 19 trials for maternal satisfaction, quality of milk expressed, and quantity of milk expressed, respectively. Many risk of bias items judged were unclear due to lack of methodological details reported, most included trials were at risk of performance bias, and there was attrition bias in some trials. The included trials were performed in a mix of high-, middle-, and low-income countries. Most but not **all included infants who were premature**. We were unable to perform planned GRADE analysis, subgroup analyses or sensitivity analyses, due to lack of data and inability to pool data from trials in analysis due to differences between trials in outcome measures. In all except one of the quantitative analysis, which included two trials, only one trial was included.

Considering the primary outcome quantity of milk expressed, and the pump/hand comparisons: There was evidence of a higher mean volume over six days pumping in the manual pump group compared with the hand expression group (MD 212.10 mls, 95% CI 9.39 to 414.81; 48 participants; 1 trial), however no evidence of a difference between these groups in volume of milk expressed on day 4-5 (MD 73.94 mls, 95% CI -64.11 to 211.99; 28 participants; 1 trial). We observed a higher mean volume over six days pumping in the large electric pump group compared with the hand expression group (MD 373.10 mls, 95% CI 161.09 to 585.11, 43 participants; 1 trial), and a higher mean volume/day assessed on day 2 (MD 15.65 mls, 95% CI 0.95 to 30.35; 26 participants; 1 trial), 3 (MD 51.11 mls, 95% CI 5.12 to 97.10; 26 participants; 1 trial), 4 (MD 100.5 mls, 95% CI 18.33 to 182.67; 26 participants; 1 trial) and 5 (MD 128 mls, 95% CI 30.64 to 225.87; 51 participant; 2 trials) in the large electric pump compared with the hand expression group. However, there was no evidence of a difference between the large electric pump and hand expression group in volume from 1 expression (MD 2.10 mls, 95% CI -0.57 to 4.77; 68 participants; 1 trial), volume/day assessed on day 6 (MD 124.87 mls, 95% CI -22.09 to 271.8; 26 participants; 1 trial) or 7 (MD 124.9 mls, 95% CI -53.37 to 303.17; 26 participants; 1 trial). We observed no difference between

hand expression for 7 days versus 3 days prior to electric pump use groups in mean volume/day assessed on day 14 (MD 117.30 mls, 95% CI -192.60 to 427.20; 34 participants; 1 trial). There was a higher mean quantity of milk in women who expressed using any method with breast massage compared with no breast massage (MD 4.82 ml, 95% CI 1.25 to 8.39; 72 participants; 1 trial).

Regarding the pump/pumping comparisons, for manual pump versus another manual pump a higher mean quantity of milk expressed over 24 hours was observed for women in the Isis pump group compared with the Evenflo pump group (MD 30.49 ml, 95% CI 3.40 to 57.58; 32 participants; 1 trial) and for women in the Harmony pump group compared with the Evenflo group (MD 28.50 ml, 95% CI 12.11 to 44.89; 32 participants; 1 trial); however no difference in this quantity of milk measures for women in the Isis compared with Harmony pump (MD 4.57 ml, 95% CI 13.42 to 22.56; 32 participants; 1 trial), Isis versus Little Heart pump (MD 15.02 ml, 95% CI -13.32 to 42.36; 32 participants; 1 trial) Harmony versus Little Heart pump (MD 12.13 ml, 95% CI -9.68 to 33.94; 32 participants; 1 trial) or Little Heart versus Evenflo pump (MD 15.47 ml, 95% CI -75.3 to 106.2; 32 participants; 1 trial) groups. There was no difference between women using any type of battery versus a small electric pump in mean volume of milk over one expression (MD 15 ml, 95% CI -8.33 to 38.33; 40 participants; 1 trial). No difference was observed between women using a large electric versus manual pump in mean volume over 6 days pumping (MD 161 ml, 95% CI -66 to 388.90; 53 participants; 1 trial), mean volume per day (MD 5.07, 95% CI -56.59 to 66.73; 145 participants; 1 trial) or mean volume expressed on day 5 (MD 150.68 mls, 95% CI -138.02 to 439.38; 27 participants; 1 trial). There was no difference between simultaneous compared with sequential pumping in mean total quantity of milk expressed over weeks 2-5 (MD 4298.94 g, 95% CI -1056.80 to 9654.68; 49 participants; 1 trial). We observed a higher mean volume of milk expressed over one expression in the large electric pump compared with battery/small electric pump group (MD 20.00 ml, 95% CI 1.28 to 38.72; 40 participants; 1 trial), however no difference between these groups in two other quantity of milk measures. For the remaining two pump/pumping comparisons no trial provided any data on quantity of milk expressed.

Considering the instruction/education and support comparisons, we observed a higher mean quantity assessed as volume on day 14 (MD 503.40 mls, 95% CI 410.76 to 595.84, 160 participants; 1 trial) with a relaxation technique compared with no relaxation technique, and the same trial showed a difference in this quantity of milk measure assessed on day 1, 5 and 10. However, another trial showed no evidence of a difference in women who expressed with and without a relaxation in change in volume/day, assessed on day seven (MD 2.24 cc, 95% CI -1.78 to 6.26; participants; 56 participants; 1 trial). We observed a higher mean change in volume of breastmilk assessed on day 7 (MD 7.60 ml, 95% CI 4.45 to 10.75; 74 participants; 1 trial) and change in volume/day assessed on day 7 (MD 58.0 ml, 95% CI 23.19 to 75.01; 74 participants; 1 trial) in women who expressed following foot massage and reflexology focused on milk production points compared to women who expressed following general foot massage. There was no clear difference observed between the group of women who received instruction support versus no specific instruction support in six quantity of milk measures. We observed a higher mean quantity of milk expressed during one expression in women who warmed the breast compared with no warming for most of the expression sessions assessed (4/6).

Considering the pumping technique or timing, comparisons, the mean milk output over 8-hours (8:00 am to 4:00 pm) on day 4 after birth was higher in women who pumped using a high vacuum pressure (-150mmHg) compared with a lower vacuum pressure (-100 mmHg) (MD 61.68 g, 95% CI 39.28 to 84.08; 98 participants; 1 trial). No data on quantity of milk expressed was provided for timing of initiation of breastmilk expression or frequency of breast expression.

In relation to quality of milk expressed (nutrients), the sodium concentration (MD -6.00 mmol/L, 95% CI -9.79 to -2.21; 118 participants; 1 trial) and protein concentration (MD -1.30 g/L, 95% CI -2.56 to -0.04; 118 participants; 1 trial) measures signalled a lower milk quality for women who expressed using a manual pump compared with hand expression. However, no difference was observed between women who expressed using a manual pump compared with hand expression in potassium concentration (MD 1.20 mmol/L, 95% CI 0.04 to 2.36; 118 participants; 1 trial), or in energy content (MD 28.20 kcal/L, 95% CI -16.94 to 75.54; 141 participants; 1 trial). The sodium concentration measure (MD -6.90 mmol/L, 95% CI -10.58 to -3.22; 111 participants; 1 trial) indicated a lower quality of milk expressed by women who used a large electric pump compared with hand expression, however we observed no difference between these groups in a range of other quality of milk measures. There was a higher fat content (Creatocrit %) in women who expressed using any method plus breast massage compared with no breast massage (MD 1.92 %, 95% CI 1.02 to 2.82; 72 participants; 1 trial), indicating that breast massage may improve quality of milk expressed. We observed a higher protein content in the milk of women who expressed using a large electric pump compared with manual pump (MD 1.40 g/L (0.08 to 2.72; 121 participants; 1 trial), suggesting a higher quality with the large electric pump. However, no difference was observed between these groups of women in sodium and potassium concentration, or in protein content of milk expressed. There was a higher fat content in milk expressed on day 1 (MD 8.60 g/L/day, 95% CI 3.66 to 13.54; 160 participants; 1 trial), day 5 (MD 12.00 g/L/day, 95% CI 5.17 to 18.83; 160 participants; 1 trial), day 10 (MD 14.00 g/L/day, 95% CI 2.25 to 25.75; 160 participants; 1 trial) and day 14 (MD 21.70 g/L/day, 95% CI 17.87 to 25.53; 160 participants; 1 trial) in women who expressed with a relaxation technique compared with no relaxation, indicating relaxation may improve quality of milk expressed. No data on quality of milk expressed were provided by the included trials for any of the other comparisons reported.

Regarding maternal satisfaction, three studies provided data suitable for analysis, assessing different measures. One study assessed satisfaction with instructions provided using the breast milk expression experience (BMEE) scale (items scored on 1-5 scale, from 1 strongly disagree to 5 strongly agree, higher score is better), and women who used the large electric pump compared with hand expression were less satisfied (MD -0.40, 95% CI -0.75 to -0.05; 68 participants). A study assessing maternal lactation (confidence) using the Chinese version of the H&H scale (20-item self-evaluated tool, higher scores represent greater satisfaction in lactation) showed a higher level of confidence at discharge (MD 5.09, 95% CI 0.01 to 10.17; 98 participants) and one month following discharge (MD 13.55, 95% CI 3.52 to 23.58; 98 participants), in mothers who expressed using a high-pressure vacuum protocol compared with a lower pressure vacuum protocol. We observed no evidence of a difference in maternal satisfaction (self-efficacy) assessed using the Breastfeeding Self-Efficacy Scale (score), between mothers who practice hand expression for seven versus for three days prior following delivery prior to expressing with an electric pump (MD -3.80, 95% CI -12.19 to 4.59; 34 participants; 1 trial).

4.2 Overall completeness and applicability of evidence

A wide range of breastmilk expression interventions have been evaluated by a large number of RCTs (51). However, the number of participants in most of the trials has been very small. Pooling results of different studies was not appropriate due to variations across trials in the types of interventions assessed (e.g. pumping equipment versus protocol for expression), variations in the details of the interventions by trials evaluating the same type of intervention, and variations in the outcome measures. Therefore, the results from most comparisons and outcomes are based on very small sample sizes and have wide standard deviations. Findings may not be applicable to women with different characteristics and in different settings to

those in the trial that produced the result. Lack of data prevented exploring if/how effects and acceptability of interventions varies by participants' characteristics such as infants gestational age at birth and time since birth. This is a serious limitation in the evidence synthesised, as the goals and effects are likely to differ between mothers of babies who are born very preterm and at term, as well as between mothers of babies during the first week postpartum, and at three months postpartum. Health professionals and lactating women therefore need to consider the result on the effects of the rich array of breastmilk expression interventions assessed in this review considering their own situations, and how they align with the characteristics of the women and babies in the trial reporting results.

Considering the comprehensiveness of the outcomes assessed, whilst a large number of relevant outcomes have been reported by RCTs evaluating effects and acceptability of breastmilk expression interventions the range is incomplete. One gap, that was noted by Becker and colleagues in their review, is the limited assessment of maternal satisfaction breastmilk expression methods, protocols and education/support, and lack of attention to assessing whether mother's own needs for milk expression are met. Very limited reporting of infant health outcomes, including growth and lack of assessment of NEC, sepsis and other illnesses that commonly affect young infants, in particular premature infants, are other gaps. Reporting of breastfeeding rates and duration outcomes has also been very limited, with the RCTs to date focusing mainly on assessing quantity and quality of milk expressed by mothers.

With regards to the completeness of interventions assessed by the available RCTs, gaps include protocols for mother-child skin-to-skin contact and proximity of the mother to her baby while expressing; design of the hospital setting (e.g. single versus shared hospital room in NICU or other ward, and other pair-wise comparisons of privacy while expressing), strategies for relaxation other than music, for example watching television; and protocols relating to frequency of expression. Interventions have been assessed by observational studies. Different lifestyle choices relating to nutrition (including alcohol consumption and smoking), which observational evidence indicates may affect breastmilk expression outcomes (e.g. volume and quality of milk) (Giglia & Binns 20016; Giglia 2010), have also not been assessed in RCTs, though ethical considerations make assessing these types of interventions in RCTs problematic.

4.3 Quality of the evidence

Many risk of bias items judged were unclear due to lack of methodological details reported, most included trials were at risk of performance bias, and there was attrition bias in some trials. We were unable to perform planned GRADE analysis, subgroup analyses or sensitivity, due to lack of data.

4.4 Potential biases in the review process

Due to the rigorous methods we used, including comprehensive searching, double screening, and careful appraisal by two reviewers, biases in the review process are likely to be low. The review team included two systematic review method experts, and a clinical expert (the lead reviewer / Master of Clinical science candidate, who is a lactation consultant). It is unlikely that trials that have been conducted have been missed, however unpublished trials, or ongoing trials not registered in clinical trial registries could be missing.

Whilst the included Becker 2016 systematic review considered studies published in any language, the search to update the Becker review considered studies published in English. Therefore, if a large number of studies meeting the review inclusion criteria with only English

reports have been published since mid-2016 (which is not likely), the review may be at risk of selective reporting bias.

The intervention inclusion criteria were designed to identify studies focused on evaluating breastmilk expression methods, including three categories/types: 1) method (e.g. pump versus hand or different types of pump compared); 2) breastmilk expression education and support; and 3) breastmilk expression protocols. During the study selection, whilst identification of relevant interventions in the first and third of these categories was straightforward, identifying relevant breastmilk expression education and support measures was not. This is because some education and support measures designed to promote breastfeeding and breastmilk feeding may have included education/support focused on breastmilk expression as a component of a more general intervention designed to support breastfeeding/breastmilk feeding. The approach we adopted, uniformly across all the studies during study selection, was to read the intervention description in the abstract or full text, and include those papers/studies for which it was clear from the intervention description that the education and/or support intervention was designed only to support breastmilk expression, or it was clear that education/support focused on breastmilk expression was a major component of the intervention. If some trials evaluated breastmilk expression education and/or support interventions as part of a broader package of interventions designed to support breastfeeding / breastmilk feeding, but did not make this explicit, they would have been excluded.

During the write up of this research project, a paper (Fewtrell 2019), reporting new results of one included study (Kennedy 2016) was identified. Additionally, a study matching the review inclusion criteria, and reporting relevant outcomes was identified (Fok 2019). The latter reports the results of an RCT assessing the effects of early initiation and regular breastmilk expression on lactogenesis II, and other breastfeeding outcomes, including quantity of milk produced by mothers. We did not include these papers, as to prevent introducing selection bias, we would have had to update the search, which would have required additional time and resources, which were not available. Inclusion of these two studies may have changed the results marginally, however, is unlikely to have changed the review conclusions (including the implications for research and practice).

4.5 Agreements and disagreements with other studies or reviews

Systematic reviews

No other systematic or other types of reviews evaluating methods of breast milk expression for lactating mothers and their infants were identified.

Considering Cochrane Reviews relating to the topic of breastmilk expression methods for lactating women, one review has assessed the effect of medication given for at least seven days to mothers of preterm infants whose breastmilk is insufficient for their infants' needs, on the outcomes of expressed milk volume and duration of breastfeeding (Donovan 2012). Selection criteria for this review were randomised and quasi-randomised controlled trials of breastmilk-augmenting medications (compared with placebo or with other augmenting medications) in mothers with preterm hospitalised infants whose breastmilk volumes failed to meet their infants' requirements. Two trials (involving 59 mothers) examining use of domperidone were included in this review. The review analysis showed a modest increase in expressed breastmilk (EBM) of 99.49 mL/day (95% confidence intervals -1.94 to 200.92; random-effects, T^2 3511.62, I^2 63%) in mothers given domperidone. Both trials gave the same dose of domperidone (10 mg three times per day) with a duration of seven days in the smaller trial and 14 days in the larger. The authors reported that neither trial showed significant improvements in longer-term outcomes of breastfeeding in the preterm population, and no

adverse effects. The authors concluded that studies suggest modest improvements in short-term EBM volumes when a medication is used after insufficient EBM occurs in mothers following preterm delivery (medication commencing ≥ 14 days post-delivery and following insufficient EBM supply with other lactation supports). Additionally, that no studies support prophylactic use of a galactagogue medication at any gestation, and further trials are required to examine larger groups of preterm mothers and consider breastfeeding outcomes over a longer period. The review by Donovan and colleagues supports the findings of this review that the available trials have small numbers of participants, that there is a dearth of data on longer-term outcomes of breastfeeding, and further trials with larger groups of women that consider breastfeeding outcomes over a longer period are warranted to guide practice relating to advice and support to enable adequate milk output in breastfeeding mothers.

A set of Cochrane reviews has examined education and support interventions to promote the initiation of breastfeeding and to increase the duration of breastfeeding and exclusive breastfeeding (Balogun 2016; Lumbiganon 2016; McFadden 2017). As Whitford et al (2017) have explained, these related reviews suggest that support interventions can be effective in singleton pregnancies. More specifically, Bologun 2016 presented some evidence that suggested breastfeeding education and peer and professional support can increase the initiation of breastfeeding (Balogun 2016), and McFadden 2017 presented evidence that support interventions by professionals or peers are effective in increasing the duration of any and exclusive breastfeeding for mothers of healthy term singletons (McFadden 2017). The evidence presented by Lumbiganon 2016 on effects of antenatal education alone was less conclusive regarding the effects, including on duration of breastfeeding (Lumbiganon 2016).

Whilst none of the above-mentioned Cochrane reviews made specific reference to education and support related to breastmilk expression, another Cochrane review, by Whitford and colleagues, evaluating the evidence on breastfeeding education and support for women with twins, highlighted education and support targeting breastmilk expression in describing the intervention. Whitford and colleagues found very little evidence, and included only two trials, one of which assessed home nurse visits versus usual care, and the other telephone peer counselling visits versus usual care (Whitford 2017). Similar to this review, the numbers of participants in the included trials were very small (15 and 27 women), the authors were unable to pool studies in meta-analysis due to differences in outcomes and interventions, and no GRADE analyses were performed. The reviewers concluded that there was insufficient evidence from randomised trials about the effectiveness of breastfeeding education and support for women with twins or high order multiples, or the most effective way to provide education and support. Additionally, they called for well-designed, adequately powered studies of interventions designed for women with twins or higher order multiples to find out what types of education and support are effective in helping these mothers to breastfeed their babies.

Considering non-Cochrane systematic reviews, Renfrew et al (Renfrew 2009) performed a systematic review to evaluate the effectiveness of clinical, public health and health promotion interventions that may promote or inhibit breastfeeding/breastmilk feeding for infants admitted to neonatal units. The inclusion criteria for the Renfrew review, were broader than this review, in particular the intervention aspect of the criteria, as the focus on interventions to promote breastfeeding/breastmilk feeding, including breastmilk expression not the latter only. More specifically, the inclusion criteria for the Renfrew 2009 review were: controlled studies of interventions intended to increase breastfeeding/feeding with breastmilk that reported breastmilk feeding outcomes and included infants admitted to neonatal units, their mothers, families and caregivers. The reviewers of the Renfrew led review noted the heterogeneity in the interventions evaluated by the trials identified for inclusion, as well as the plethora of outcome measures, which is similar to the finding of this review. Due to this heterogeneity,

narrative synthesis only was performed by Renfrew et al. Forty-eight studies were included in the review overall, with 21 studies identified as good quality included in the synthesis informing main results and review conclusions. The main results included that simultaneous breastmilk expression is an effective intervention for breastfeeding promotion. Other effective interventions identified were kangaroo skin-to-skin contact, peer support in hospital and community, multidisciplinary staff training, and UNICEF Baby Friendly accreditation of the associated maternity hospital. The Renfrew review (Renfrew 2017) identified health outcomes and costs of intervening with less clinically stable infants as one of the evidence gaps.

Oliveira et al (2016) performed a meta-analysis of education interventions for breastfeeding promotion directed to the women and her social network, including 11 studies in the main review analysis, which compared any educational interventions with routine care. The review found that educational interventions were about twice as effective compared with routine interventions. It is unclear whether education focused on breastmilk expression was a key component of the interventions assessed by the trials included in this review, as breastmilk expression was not considered separately in the review analysis (i.e. no sub-group for intervention type with breastmilk expression as one of the types).

Other studies

In a descriptive comparative study, Dowling 2012 examined differences in breastmilk expression outcomes before and after implementation of a single-family room (SFR) neonatal intensive care unit (NICU). A sample of 40 women was included in the study, 15 in the original NICU, and 25 in the SFR NICU. Nutritional data were collected throughout hospitalization. Mothers used a milk expression diary during hospitalization and completed a survey about their experiences with milk expression, completed immediately before hospital discharge. The study observed: a high proportion of mothers (75%) planned to express before delivery; the majority of mothers were most comfortable pumping in their own homes because of the increased privacy; no statistical difference between the two groups (SFR versus shared), in the place where they were most comfortable pumping or where they usually pumped, although more mothers pumped in their babies rooms in the SFR NICU. Additionally, the study found that the majority of the mothers reported concern about their milk supply at some time during hospitalisation, and 47.5% reported having breast problems. There were no significant differences between the groups in quantity of milk expressed between the mothers who expressed after the implementation of a SFR, compared to mothers who expressed before. Dowling and colleagues concluded that individual mothers need for privacy need to be determined and interventions to support mothers' feeding plans throughout hospitalization and at discharge need to be developed. The Dowling study assessed a unique and important intervention, not assessed by any of the trials included in this review, and points towards a gap in the evidence base of RCTs identified in this review, that should be addressed in future trials (as argued above). The finding that it is important to consider mother's own goals and preference when designing, implementing and assessing interventions to support breastmilk expression (and thereby breastfeeding and breastmilk feeding) agrees with this review (and the Becker 2016 systematic review).

Healy 2016 reported an observational study (pre- and post-intervention design) conducted to assess neonatal outcomes following implementation of a structured, practical approach for promotion of breastmilk expression in mothers of very preterm infants. The study was undertaken at the Department of Neonatology at Cork University Maternity Hospital (CUMH), Cork, Ireland. Infants were included in the study if they were admitted to the NICU after birth at a gestation of less than 32 weeks, or at a birthweight of less than 1500 g. In this study, a multidisciplinary team developed a protocol to test a package of interventions.

Appendix 7 provides the intervention protocol for this study, understanding the range and details of the interventions assessed requires reading the protocol. The measures included education focused on how to use the pump, actions to ensure access to pumping equipment, support (various forms of relaxation promoted), protocols relating to timing (including expressing as early as possible after birth) and recommendations relating to healthy lifestyle, including smoking and alcohol consumption. Advice about how to collect milk, store milk, transport milk, and sterilize pumping equipment to minimise contamination, was also included. The study protocol included a tool (table) for mothers to record the volume of milk expressed. The intervention was delivered through an information pack and face-to-face consultation with nursing staff. Outcomes assessed included breastmilk expression, initiation of feeding, re-attainment of birthweight, attainment of full enteral feeding, the incidence of NEC, sepsis and duration of hospitalisation. A total of 82 infants were included (39, 43). While no statistical differences were observed in earlier initiation of enteral feeding with EMB (median = 2 days) nor earlier achievement of fully enteral feeding (median = 12 days), birthweight was regained earlier in the postintervention cohort (mean = 10.42 days; $p = 0.083$), and there was a reduced length of stay (mean = 50 days; $p = 0.021$). This study is different from the studies included in this review not only in its design, but also in its multi-modal intervention approach, and the array of outcomes reported (none of the studies included in this review reported NEC, and only one reported the outcomes infant weight and infant length of hospital stay).

A quasi-experimental study based on a convenience sample (Divya 2016) evaluated the effect of breast massage on breastmilk expression in mothers of neonates admitted to NICUs. The breast massage was taught to mothers with the assistance of a video. The massage included rubbing, stroking and kneading each breast followed by massaging breast with finger pads, in a circular motion around the whole breast in a clockwise manner. Two of the primary outcomes included in this review were evaluated in this before-after intervention study: quantity of milk expressed (measured over three sessions), and maternal satisfaction. The BMEE scale (5-point Likert scale developed by Flaherman to evaluate women experience of expressing milk; a higher score is better). The study observed a higher volume of breastmilk produced after the intervention (mean pre-test volume of expressed milk in millilitres was 7.33 SD 4.86 prior to intervention, increased to 15.56 SD 8.38 after the intervention, $t = 4.22$, $p = 0.001$). This finding is in agreement with the finding based on very limited RCT evidence in this review, that breastmilk expression with breast massage may produce a higher quantity of expressed breastmilk compared to breastmilk expression without breast massage. Maternal satisfaction with breastmilk expression in the post-test, mean 37.6, SD 3.88, was significantly higher than in pre-test, 28.4, SD 4.73 ($t = 11.25$, $p = 0.001$).

Blatz and colleagues (Blatz 2017) evaluated effects of a breastmilk expression and support education and support intervention targeted at mothers providing breast milk for their preterm hospitalized infants, in a small descriptive study ($n=18$ mothers who used the site). The intervention was delivered through a password protected Web site. The descriptive study had no comparison group. The study authors reported that the intervention for the mothers of preterm infants was designed to “educate them about breastmilk expression and assist them in monitoring their breast milk supply” (Blatz 2017, pp.222). The study observed that mothers used the site (13/18 logged on consistently), and most mothers reported that they found the education provided through the site valuable. The authors of this study concluded, similar to our review, that education and support may have a positive effect on breastmilk expression, even though it lacked detailed evidence on the level and nature of effects on different outcomes. The authors concluded that it is important to test electronic health application education and support measures for women who are expressing milk for their preterm infants, a suggestion that aligns with the research recommendations of this review.

Goodchild et al 2018 recently conducted an evidence implementation project on assessing and changing breastmilk expression practice in the NICU at the Women's and Children's Hospital in Adelaide, using the Joanna Briggs Institute Practical Application of Clinical Evidence System (JBI-PACES) and Getting Research into Practice (GRiP) audit and feedback tool. The focus of the project was on designing and implementing a protocol for breastmilk expression (based on a literature review of available evidence and guidelines, and consultation with expert clinicians), and testing change in practice, rather than assessing effects of any one (or more) breastmilk expression intervention on specified feeding, infant/maternal health and other outcomes, or maternal satisfaction with expression. The implementation project observed substantial changes in practices, in the form of following mothers and health staff following the new protocol, signalling the importance of building the evidence base on effective, and the most effective methods of breastmilk expression for lactating women and their infants.

4.6 Conclusion

There is a moderately large but diffuse body of RCT evidence (51 trials) reporting effects of: 1) a range of breastmilk expression interventions compared with standard care; and 2) different types of breastmilk expression interventions, on a number of relevant outcomes, including quantity and quality of breastmilk expressed. Few of these RCTs trials have assessed maternal acceptability of few breastmilk expression interventions. Lack of detailed reporting of methods is a feature of most trials that have evaluated breastmilk expression interventions, which makes confident assessment of the risk of bias of the trials overall difficult.

Diversity of interventions and outcomes assessed across the trials, prohibits combining data from trials in meaningful meta-analysis and performing GRADE evidence quality assessment for important and critical outcomes. Sub-group analysis to tease out possible variations in effects and acceptability by characteristics of women and their babies (including gestational age at birth, and length of time since birth), is not feasible with the data available from trials assessing breastmilk expression methods.

The RCT evidence for effective methods of expressing for lactating women is therefore not yet clear.

4.7 Implications for practice

There is limited evidence from individual small trials that suggests pumping with an electric pump or manual pump produces a higher quantity of milk compared with expressing by hand. There is also evidence from single small trials indicating pumping supported by a relaxation technique (e.g. listening to music, foot massage) and with breast massage, may result in a higher milk volume. Additionally, limited evidence suggests hand expression can in certain circumstances lead to high quality of milk than pumping using a manual or large electric pump. RCT evidence on maternal preference for different breastmilk expression methods is very limited, though one study suggests that some women may be more satisfied with hand expression than using an electric pump.

The RCT evidence is context specific and insufficient to guide practice. Whilst health professionals should consider breastmilk expression support measures (including relaxation) and education about potentially effective protocols such as a massage, it offers no direction on the intervention types and features that are likely to be most beneficial and appropriate for women in different situations. Clinical judgement informed by the circumstance and preferences of the patient is therefore required.

4.8 Implications for research

Future high quality RCTs assessing the effects of breastmilk expression interventions compared to standard care, and the effects of different types of breastmilk expression interventions are required.

Future studies should assess the full range of interventions that existing studies (including observational), and existing practice and clinical expertise have identified as having potential to impact on quantity of breastmilk expressed, quality of expressed milk, and maternal acceptability. Studies assessing combined interventions should be considered by trialists.

It is important that studies assess the full range of outcomes that experts (e.g. lactation consultants and neonatologists) identify as important to assess in order to promote, efficiently, breastmilk feeding and breastfeeding. Inclusion of measures of cost, and acceptability in the core set of outcomes assessed is important to inform efficient and effective implementation of guidelines that will be developed.

To facilitate pooling of outcomes from different studies in future meta-analysis, and thereby produce certain evidence on effects to inform guidelines and guide practice towards better outcomes for mothers and infants, studies should use similar measures of outcomes, and assess outcome at critical common timepoints.

As the effects and acceptability of breastmilk expression interventions are likely to vary depending on characteristics of mother-infant dyads (including but not limited to gestational age at birth, singletons versus multiples, time since birth, mode of birth, mother health), trials should consider collecting data and stratifying analysis to enable explore these potential effect modifiers. Additionally, future systematic reviews on the effects and acceptability of breastmilk expression intervention should include meta-analysis with sub-group analysis exploring if/how effects and acceptability varies by these participant characteristics, as well as details of intervention features (e.g. who delivers the intervention, duration of education interventions).

If future studies assess breastmilk expression education and support interventions as part of education and support interventions focused on breastfeeding promotion more broadly, trialists should clearly identify the breastmilk expression intervention(s) assessed, and report results for each separately.

Appendix 1: NHMRC levels of evidence for developers of guidelines

Level	Intervention ¹	Diagnostic accuracy ²	Prognosis	Aetiology ³	Screening Intervention
I ⁴	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, ⁵ among consecutive persons with a defined clinical presentation ⁶	A prospective cohort study ⁷	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, ⁵ among non-consecutive persons with a defined clinical presentation ⁶	All or none ⁸	All or none ⁸	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> ▪ Non-randomised, experimental trial ⁹ ▪ Cohort study ▪ Case-control study ▪ Interrupted time series with a control group 	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> ▪ Historical control study ▪ Two or more single arm study ¹⁰ ▪ Interrupted time series without a parallel control group 	Diagnostic case-control study ⁶	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> ▪ Historical control study ▪ Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard) ¹¹	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

Definitions

Systematic Review: systematic location, appraisal, and synthesis of evidence from scientific studies.

Randomised controlled trial: the unit of experimentation (e.g. people, or a cluster of people) is allocated to either an intervention (the factor under study) group or a control group, using a random mechanism (such as a coin toss, random number table, computer-generated random numbers) and the outcomes from each group are compared. Cross-over randomised controlled trials are considered to be the same level of evidence as RCT's though appraisal of these trials would need to be tailored.

Pseudo-randomised controlled trial: the unit of experimentation (e.g. people, a cluster of people) is allocated to either an intervention (the factor under study) group or a control group, using a pseudo-random method (such as alternate allocation, allocation by days of the week or odd-even study numbers) and the outcomes from each group are compared.

Non-randomised, experimental trial - the unit of experimentation (e.g. people, a cluster of people) is allocated to either an intervention group or a control group, using a non-random method (such as patient or clinician preference/availability) and the outcomes from each group are compared. This can include:

- **A controlled before-and-after study**, where outcome measurements are taken before and after the intervention is introduced, and compared at the same time point to outcome measures in the (control) group.
- **An adjusted indirect comparison**, where two randomised controlled trials compare different interventions to the same comparator i.e.. the placebo or control condition. The outcomes from the two interventions are then compared indirectly. An adjusted indirect comparison compares single arms from A vs B and B vs C allows a comparison of A vs C when there is statistical adjustment for B. This is most commonly done in meta-analyses.

Cohort study: outcomes for groups of people observed to be exposed to an intervention or the factors under the study, are compared to outcomes for groups of people not exposed

- **Prospective cohort study:** where groups of people are observed at a point in time to be exposed or not exposed to an intervention (or the factor under the study) and then are followed prospectively with further outcomes recorded as they happen.
- **Retrospective cohort study:** where the cohorts (groups of people) are defined at a point in time in the past and information collected on subsequent outcomes e.g. the use of medical records to identify groups of women using oral contraception five years ago vs women who were not using oral contraceptives, and then contacting these women or identifying subsequent medical records of the development of deep vein thrombosis.

Case-control study: people with the outcome or disease (cases) and an appropriate group of controls without the outcome or disease (controls) are selected and information obtained about their previous exposure/non-exposure to the intervention or factor under study.

Interrupted time series with a control group: trends in an outcome or disease are measured over multiple time points before and after the intervention is introduced to a group of people and then compared to the outcomes at the same time points for a group of people that did not receive the intervention.

Historical control study: outcomes for a prospectively collected group of people exposed to the intervention (factor under study) are compared with either (1) the outcomes of people treated at the same institution prior to the introduction of the intervention (i.e. control group/usual care), or (2) the outcomes of a previously published series of people undergoing the alternate or control intervention.

Two or more single arm study: the outcomes of a single series of people receiving an intervention (case series) from two or more studies are compared.

Interrupted time series without a parallel control group: trends in an outcome or disease are measured over multiple time points before and after the intervention is introduced to a group of people, and compare (as opposed to being compared to an external control group).

Case series: a single group of people exposed to the intervention

- **Post-test:** only outcomes after the intervention are recorded in the series of people, so no comparisons can be made
- **Pre-test/post-test:** measures of an outcome are taken before and after the intervention is introduced to a series of people and are then compared.

A study of test accuracy with an independent, blinded comparison with a valid reference standard, among consecutive patients with a defined clinical presentation: a cross-sectional study where a consecutive group of people from an appropriate (relevant) population receive the test under study (index test) and the reference standard test. The index test result is not incorporated in (is independent of) the reference test result/final diagnosis. The assessor determining the results of the index test is blinded to the results of the reference standard test and vice versa.

A study of test accuracy with an independent, blinded comparison with a valid reference standard, among non-consecutive patients with a defined clinical presentation: a cross-sectional study where a non-consecutive group of people from an appropriate (relevant) population receive the test under study (index test) and the reference standard test. The index test result is not incorporated in (is independent of) the reference test result/final diagnosis. The assessor determining the results of the index test is blinded to the results of the reference standard test and vice versa.

Diagnostic (test) accuracy: in diagnostic accuracy studies, the outcomes from one or more diagnostic tests under evaluation (the index test/s) are compared with outcomes from a reference standard test. These outcomes are measured in individuals who are suspected of having the condition of interest. The term accuracy refers to the amount of agreement between the index test and the reference standard test in terms of outcome measurement. Diagnostic accuracy can be expressed in many ways, including sensitivity and specificity, likelihood ratios, diagnostic odds ratio, and the area under a receiver operator characteristic (ROC) curve.

Historical control study: outcomes for a prospectively collected group of people exposed to the intervention (factor under study) are compared with either (1) the outcomes of people treated at the same institution prior to the introduction of the intervention (i.e. control group/usual care), or (2) the outcomes of a previously published series of people undergoing the alternate or control intervention.

All or none: all or none of a series of people with the risk factor experience the outcome. The data should relate to an unelected or representative case series which provides an unbiased representation of the prognostic effect.

Source: NHMRC (2009) NHMRC additional levels of evidence and grades for recommendations for developers of guidelines.

Appendix 2: PICO(s) eligibility criteria table

Population	Intervention	Comparator	Outcomes	Study design
<p>Studies including women expressing or pumping milk any time after birth, located in any country and hospital (or other type of health service), or community setting, who may or may not be feeding a child at the breast.</p> <p>Studies including term and/or preterm infants, singles or multiples, were eligible for inclusion.</p> <p>There were no restrictions on health status of mother or child.</p>	<p>Breastmilk expression interventions, including: 1) pumping equipment and method (e.g. pump, hand expression); 2) protocols relating to timing of expression (initiation, frequency, duration) and/or technique (e.g. pressure); 3) breastmilk expression education and support (e.g. relaxation)</p> <p>Single and combined interventions were eligible.</p> <p>Pharmacological treatments were excluded.</p>	<p>1) Standard care 2) Breastmilk expression interventions (i.e. pairwise comparisons of different interventions considered)</p>	<p>Primary</p> <ul style="list-style-type: none"> Quantity of milk expressed (all time points and measures reported) Quality of milk expressed (e.g. nutrient, fat, energy content in milk) Maternal satisfaction (or lack of maternal satisfaction) with the method of expression, including acceptability, comfort, ease of uses and achievement of woman's goal(s) for expressing <p>Secondary</p> <p><i>Feeding</i></p> <ul style="list-style-type: none"> Breastfeeding (rates at various time points, up to six months after birth, and duration) Transfer to feeding at the breast (if not initially feeding at the breast) Time of initiation of breast milk expression Maternal physiological effects of expressing or pumping (e.g. time to lactogenesis stage II, prolactin and other hormone levels) <p><i>Maternal health</i></p> <ul style="list-style-type: none"> Depression, anxiety and stress measures (all scales with a rationale provided, as reported) Other measures of wellbeing (all scales with a rationale provided, as reported) <p><i>Infant health</i></p> <ul style="list-style-type: none"> Growth Length Head circumference <p><i>Adverse effects for mother or infant</i></p> <ul style="list-style-type: none"> Contamination of expressed breastmilk e.g. bacterial level in expressed milk (Dornic degrees of acidity) Reduction or cessation of pumping or expressing due to difficulties experienced Other (e.g. nipple pain, engorgement, damage to the breast) <p><i>Acceptability</i></p> <ul style="list-style-type: none"> Time taken to express milk Infant length of hospital stay Cost: cost of pumping equipment (for mother/family); cost to healthcare facility of supporting expression method/pump equipment, protocol or education and support 	<p>Randomised controlled trials and study arms of randomised controlled trials.</p> <p>Cluster randomised controlled trials and cross over trials were eligible.</p> <p>Cross over trials were eligible.</p> <p>Systematic reviews were eligible.</p> <p>We included trials published as abstracts only provided they reported at least one relevant outcome (data or narrative).</p> <p>Languages other than English were excluded.</p>

Appendix 3: Calculation of design effect factor for included cluster RCT

Study	Average cluster size (M) used to compute design effect ¹	ICC used to compute design effect	Design effect factor used in review analyses
McLachlan 2016	71.1	0.03	3.103

Abbreviations: **ICC**: intra cluster correlation coefficient; **M**: average cluster size.

¹ Design effect = $1 + (M-1) \times ICC$

Appendix 4: Characteristics of included studies tables

Becker 2016	
Methods	<p>Design: systematic review of RCTs comparing breast milk expression methods at any time after birth.</p> <p>Search: Cochrane Pregnancy and Childbirth Group search (last updated 21 March 2016). English language only included.</p> <p>Selection criteria:</p> <p><i>Participants:</i> Women expressing or pumping milk for any reason by any method, who may or may not also be feeding a child at the breast. The health status of the child was not a defining criterion for inclusion or exclusion. Term and preterm, singleton and multiple births, as well as hospitalised and non-hospitalised mother-infant pairs were included.</p> <p><i>Interventions:</i></p> <ul style="list-style-type: none"> • instructions (oral, written or other media) or support protocol on hand expression, or mechanical pumping specifically for the study; or • hand expression or mechanical pumping equipment; or • expression or pumping using a specific protocol or adjunct behavior (for example frequency of expression, length of time to express, breast massage, relaxation, imagery, conditioning process, expressing breasts sequentially or simultaneously) or • support program specific to milk expression <p><i>Comparisons:</i> any instruction or support protocol on hand expression or mechanical pumping, pumping equipment or hand expression, expression or pumping using a specified protocol or adjunct behavior; support program specific to milk expression</p> <p><i>Outcomes</i></p> <p><u>Primary:</u> 1) indicators of maternal satisfaction (or lack of) with method, including acceptability, comfort, ease of use, and achievement of the woman's goal for expressing or pumping; 2) indicators of possible adverse outcomes for mother or infant as a result of pumping or expressing including contamination of milk, injury to mother's breast or other anatomy, reduction or cessation of pumping or expressing due to difficulties with pumping or expressing;</p> <p><u>Secondary:</u> transfer to feeding at the breast if expressing preceded feeding at the breast, quantity of milk expressed, time taken to express milk, nutrient quality of expressed milk (e.g. fat, sodium, energy), maternal physiological effects of expressing (prolactin and other hormone levels), economic (cost of pumping, length of hospital stay for infant, level of healthcare service usage to support expressing or pumping).</p> <p>Data collection and analysis: Cochrane protocol followed. (as per Handbook, see Higgins 2011).</p>
Included studies, participants and settings	<p>41 trials included (n = 2293 mothers and their infants randomized in the included trials).</p> <p>Twenty-six of the trials included preterm or ill infants (in neonatal units); 14 trials included healthy term infants; one trial included neonatal and healthy older infants.</p> <p>USA (n=23); UK (n=4); Australia (2); India (2); Canada (2); Malaysia (1); Brazil (1), Egypt (1), Mexico (1), Israel (1), Ecuador (1), Turkey (1), Kenya and Nigeria (1).</p>

Interventions in included trials	<p><u>Trials assessing pumping equipment or method (e.g. hand):</u> eleven studies hand expression and pumping (Boo 2001; Flaherman; Garza 1982; Lussier 2015; Mangel 2015; Paul 1996; Pessoto 2010; Pittard 1991; Slusher 2007; Vasani 2004; Zinaman 1992); 14 studies included two or more different types of pumps or pump vacuum patterns (Barnabe-Garcia 2012; Boutte 2013; Burton 2013; Fewtrell 2001a; Fewtrell 2001b; Francis 2008; Hayes 2008; Hopkinson 2009; Pessoto 2010; Rasmussen 2011; Slusher 2007; Zinaman 1992).</p> <p><u>Education and support measure(s):</u> provision of a milk expression education and support intervention tailored for mothers of preterm infants, 3 studies (Ahmed 2008; Heon 2011; Pinelli 2001); breast massage before pumping, 2 studies (Jones 2001; Stuetz 1988); therapeutic touch, 1 study (Mersmann 1993); breast warming before pumping, 1 study (Yigit 2012); education focused on how to pump using hands and electric pump versus pump only, 1 study on women taught “Hands on Pumping” (Stellwagen 2010; abstract only, no data included in the Becker review)</p> <p><u>Protocols relating to expression timing or technique:</u> sequential versus simultaneous pumping protocols, five studies (Auerbach 1990; Groh- Wargo 1995; Hill 1999; Jones 2001; Prime 2012); frequency of expression, one study (De Carvalho 1985); timing of initiation of breast milk expression, one study (Parker 2012); breast shield size, one study (Prime 2010); breast cleansing protocol, one study (Costa 1989; no outcomes data provided, therefore no results included in the Becker review)</p>
Comparisons assessed	<p>N =17 in total, of which n = 13 included had quantitative outcomes data in the review analyses and n = 4 had narrative outcome reports only.</p> <ol style="list-style-type: none"> 1) Any type of pump versus hand expression 2) Any manual pump versus hand expression 3) Any manual pump versus any other manual pump 4) Any battery or small electric pump versus any other battery or small electric pump 5) Any large electric pump versus hand expression 6) Any large electric pump versus manual pump 7) Any large electric pump versus battery or small electric pump 8) Any method with a specified protocol of simultaneous versus sequential pumping 9) Any method with a specified relaxation technique versus no specified relaxation technique 10) Any method plus specific instruction or support provided versus any method with no specific instruction provided 11) Any method plus breast massage versus no breast massage 12) Any method plus warming the breast versus not warming the breast 13) Any vacuum protocol versus vacuum protocol 14) Any manual pump versus small electric/ battery hand held pump 15) Different timing of initiation of breast milk expression (within 1 hour versus between 1-6 hours) 16) Larger size breast shield versus smaller size breast shield 17) Frequency of breast expression (≥ 4 times per day versus ≤ 3 times per day)
Notes	<p>Funding sources: no commercial funding sources declared, therefore funding unlikely to have affected risk of bias in the review.</p> <p>Author declarations of interest: none declared</p>

Risk of bias (assessed using the ROBIS tool for appraising systematic reviews, see Whiting 2016 for tool)						
Domain	Risk of bias					
	Y	PY	PN	N	NI	Rationale for concern
1 STUDY ELIGIBILITY CRITERIA: Describe the study eligibility criteria, any restrictions on eligibility and whether there was evidence that objectives and eligibility criteria were pre-specified:						
1.1 Did the review adhere to pre-defined objectives and eligibility criteria? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Eligibility criteria clear, if broad in scope, particularly regarding interventions. Objective less clear, particularly with respect to signaling the range of interventions included in the review.
1.2 Were the eligibility criteria appropriate for the review question? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Need some text to justify?
1.31.3 Were eligibility criteria unambiguous? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes, aside from lack of clarity regarding range of interventions included in the expression protocol
1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	As above

format, language, availability of data)? (Y/PY/PN/N/NI)						
Concerns regarding specification of study eligibility criteria (LOW/HIGH/UNCLEAR)	LOW					
2 IDENTIFICATION AND SELECTION OF STUDIES: Describe methods of study identification and selection (e.g. number of reviewers involved):						
2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Wide range of electronic databases searched (standardized set searched in reviews performed by members of the Cochrane Pregnancy and Childbirth Group. Unpublished studies sought via contacting experts in the field and email alerts.
2. Were methods additional to database searching used to identify relevant reports? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Hand search, email alerts and contacting experts.
2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Review authors report that an Information specialist from the Cochrane Pregnancy and Childbirth Groups performed the search. Search strategy used to retrieve potentially relevant records from one database reported (see Appendix 1) and is appears likely to have retrieved potentially relevant studies.
2.4 Were restrictions based on date, publication format, or language appropriate? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	No restrictions on date or language.
2.5 Were efforts made to minimise error in selection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Three reviewers (all authors of the review), conducted the study selection.

of studies? (Y/PY/PN/N/NI)						
Concerns regarding methods used to identify and/or select studies (LOW/HIGH/UNCLEAR)	LOW					
3 DATA COLLECTION AND STUDY APPRAISAL: Describe methods of data collection, what data were extracted from studies or collected through other means, how risk of bias was assessed (e.g. number of reviewers involved) and the tool used to assess risk of bias:						
3.1 Were efforts made to minimise error in data collection? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Data extracted by two reviewers who worked independently.
3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appropriately populated characteristics of included study tables reported for all 41 of the included trials.
3.3 Were all relevant study results collected for use in the synthesis? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	As above
3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All included trials assessed using the Cochrane Risk of Bias assessment tool for appraising randomised and non-randomised trials in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).
3.5 Were efforts made to minimise error in risk of bias assessment? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Two reviewers assessed ROB, and worked independently, with disagreements resolved by a third reviewer.

Concerns regarding methods used to collect data and appraise studies (LOW/HIGH/UNCLEAR)	LOW					
4 SYNTHESIS AND FINDINGS: Describe synthesis methods						
4.1 Did the synthesis include all studies that it should? (Y/PY/PN/N/NI) Was between-study variation (heterogeneity) minimal or addressed in the synthesis? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The authors did not address heterogeneity in the synthesis, however this was because only one trial was included in meta-analysis, for all the reported outcomes. In the methods sections of the review, the authors report that had data been reported from more than one trial, they would have assessed and if necessary, explained statistical heterogeneity.
4.2 Were all pre-defined analyses reported or departures explained? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The authors report that pre-specified exploration of heterogeneity, assessment of selection bias (via funnel plots), and sensitivity analysis were not conducted due to data limitations (only one trial reporting on each outcome).
4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis? (Y/PY/PN/N/NI)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	See comment for question 4.1 above.
4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Lack of data in meta-analysis meant the reviewers were unable to assess robustness through limiting meta-analysis to high quality studies, and assessment of funnel plots. They commented on this limitation in the main text of the review.

4.6 Were biases in primary studies minimal or addressed in the synthesis? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	With one study included in each of the meta-analysis the quality of each study/limitations of the evidence for each outcome is clear (transparent).
Concerns regarding methods used to synthesize (LOW/HIGH/UNCLEAR)	LOW					
5 Other						
A. Did the interpretation of findings address all the concerns identified in Domains 1 to 4? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The reviewers follow standard protocol for systematic reviews, and appropriately identify, synthesize and assess the available evidence on breastmilk expression methods for lactating women. However, their interpretation of the evidence, in particular recommendations for practice are inappropriate as having presented results of only one small to moderate size study for all comparisons and outcomes (except for one outcome and comparison, which includes two small studies), they make recommendations for practice about what may be effective interventions.
B. Was the relevance of identified studies to the review's research question appropriately considered? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
C. Did the reviewers avoid emphasizing results on the basis of their statistical significance? (Y/PY/PN/N/NI)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The reviewers drew conclusions about promising and acceptable interventions based on statistically significant results only, from analysis based on only one trial (with mostly few participants), and without any formal evidence quality assessment (e.g. using the GRADE approach).
Risk of bias in the review: LOW/HIGH/UNCLEAR	LOW However, note there is a concern about the way the reviewers have interpreted the evidence, and made recommendations for practice. Some conclusions and recommendations are drawn when certainty and direction are not warranted by the nature of the evidence synthesized (only one study with small to moderate numbers of participants included in analysis, for all except one comparison and outcome, for which only two small studies were included).					

Demirci 2016		
Methods	RCT	
Participants	<p>11 lactating women were randomised</p> <p>Inclusion criteria: Initial screening for mothers with late preterm or early term infants (i.e. born between 34- and 37+6-week's gestation) currently providing breast milk and intending to provide breastmilk exclusively for minimum of two months. Women meeting these criteria were followed up with a telephone call at 1-2 weeks postpartum and assessed for two additional inclusion criteria: breastfeeding or expressing at least 6 times a day and a perception of low or insufficient supply.</p> <p>Exclusion criteria: any conditions with a potential to affect milk supply (e.g. hypothyroidism, polycystic ovary disease).</p> <p>Setting: USA</p>	
Intervention	<p>Group 1 (n = 5): Women received an MP3 player (Apple iPod Shuffle) with three guided meditations of 5-8 minutes each. They were instructed to listen to meditations of their choice from those supplied at least twice a day, preferably when breastfeeding or expressing breast milk. The meditations included a guided imagery recording specific to breastfeeding, a guided thankfulness meditation (Loving-Kindness), and a guided relaxation (body scan). Participants also received three visits with a lactation consultant, which included infant weight-measurement and breastfeeding assistance. Women kept a diary of intervention use, side effects, infant feeding (breast milk feeds & volume), concern about supply.</p> <p>Group 2 (n = 6): Women received a commercially available herbal supplement (Motherlove: More Milk Plus Alcohol Free) containing fenugreek, blessed thistle, nettle and fennel. Women assigned to this group were instructed to add the oral tincture to a palatable liquid <1oz and drink it 3 to 4 times a day. Timing and dosage of the supplement were based upon the mother's current weight, as advised by the manufacturer. The herbal tincture was reported by the manufacturer to be effective in increasing milk supply in 1 to 2 days. Like those in the intervention group, these women received three visits with a lactation consultant, which included infant weight-measurement and breastfeeding assistance.</p>	
Outcomes	<p>Data: secondary i) breastfeeding (any) at 2 months</p> <p>Narrative: none</p>	
Notes	<p>Funding: Ruth Perkins Kuehn Research Award – University of Pittsburgh School of Nursing; National Institutes Pathway to Independence.</p> <p>Declarations of Interest: none declared.</p>	
ROB	Authors' judgement	Support for judgement
Random Sequence Generation	Low risk	"Computer-generated block randomization was used to ensure near-equal allocation to each group in this small sample."
Allocation Concealment	Unclear risk	No information on how allocation concealed during randomisation provided.
Blinding of participants and personnel	High risk	Participants, not feasible; personnel, not reported.

Blinding of outcome assessment	High risk	The women and study personnel who assessed the study outcomes were not blinded, and the outcomes were not objective, therefore may be subject to bias.
Incomplete Outcome Data	Low risk	11 women randomised, 5 to intervention and 6 to control group and all completed the 9-day study.
Selective Outcome Reporting	Unclear risk	Without access to protocol not possible to assess.
Other bias	High risk	Unclear whether participants similar at baseline (no baseline data comparing characteristics of groups); underpowered to detect intervention effect (goal was to enroll a sample of 20-25 women, 11 only included).

Kennedy 2016		
Methods	RCT: NCT0212895 (published abstract available only)	
Participants	109 lactating women were randomized Inclusion criteria: mothers of term infants, at 6 weeks postpartum Exclusion criteria: not reported Setting: Multi-country trial, performed In Beijing, Moscow, London and New York (Infants < 1 month of age)	
Intervention	Group 1 (n = not reported) Mothers were provided with a Philips AVENT Comfort +Natural single electric pump/bottle system at 6 weeks postpartum and requested to express for 10 minutes per breast, mothers determined pump/ bottle use. Group 2 (n = not reported) Mothers were provided with a Medela Swing + Calma Single electric pump/ bottle system at 6 weeks postpartum, and requested to express for 10 minutes per breast, using this pump. Mothers determined pump/ bottle use).	
Outcomes	Data: none Narrative: quantity of milk expressed	
Notes	Funding & Declaration of interest: not reported Declarations of interest: not declared	
ROB	Authors' judgement	Support for judgement
Random sequence generation	Unclear risk	Authors state that: "women were randomised", no further details.
Allocation concealment	High risk	Method used to conceal allocation not reported.
Blinding of participants and personnel	Unclear risk	Not reported.
Blinding of outcome assessment	Unclear risk	Insufficient information reported
Incomplete outcome data	Unclear risk	Attrition not reported
Selective outcome reporting	High risk	No study protocol available to confidently assess; missing data (no numbers of participants and events in each group), in the abstract and short report included with limited outcomes.
Other bias	Unclear risk	Insufficient details on methods provided on methods to confidently assess as low or high risk of bias.

Lawrence 2017		
Methods	RCT: NCT01893047 (multi-arm, cross-over design)	
Participants	<p>33 women and their infants were randomized to 186 sessions (each woman served as own control)</p> <p>Inclusion criteria: first time mother at 7-10 days postpartum, age 18 to 45, had a vaginal or caesarean delivery well, with an infant born at less than 32.0 weeks of gestation, intending to breastfeed and planning to pump milk on site in the NICU at least once/day recruited 7-10 days postpartum. Mothers who smoked, were taking medication that may interfere with breastfeeding, and who have undergone prior breast surgery were included on the basis that they were serving as their own controls. Additionally, mothers must have been able to understand the study protocol and sign a consent form in English.</p> <p>Exclusion criteria: mothers of infants with a low likelihood of survival as determined by the attending physician, mothers who have been diagnosed with mastitis.</p> <p>Setting: Neonatal or neonatal intensive care unit in New York hospital (recruitment or study dates not reported)</p>	
Intervention	<p>Group 1 (n = 33 women, 62 sessions) Breastmilk expression using the Symphony Breast pump Medela that was standard for use in the NICU where the study was performed. The mother decided if she pumped one or both breasts at a time. Whatever condition she chose remained the same throughout all study sessions.)</p> <p>Group 2 (n = 33 women, 62 sessions) Breastmilk expression using the same method as used for the group 1 intervention, however listening to music of choice (country, hip-hop or classical)</p> <p>Group 3, control (n = 33 women, 62 sessions) Standard care (i.e. pumping as described for group 1 and 2, without listening to music while expressing).</p> <p>In all the sessions, the mother pumped her milk into an 80cc Volufeed container. Only one breast pumping session was assessed on a given day, for all interventions and outcomes.</p>	
Outcomes	<p>Data: none</p> <p>Narrative: <u>primary</u> i) quantity of milk expressed; ii) acceptability (maternal satisfaction)</p>	
Notes	<p>Funding & Declaration of interest: not reported.</p> <p>Declarations of interest: not declared.</p> <p>Conference abstract reporting results for this study available only (in addition to the protocol at http://clinicaltrials.gov/ctct2/show/NCT01893047)</p>	
ROB	Authors' judgement	Support for judgement
Random sequence generation	Unclear risk	Insufficient information in conference abstract or trial website to assess.
Allocation concealment	Unclear risk	Insufficient information in conference abstract or trial website to assess.
Blinding of participants and personnel	Unclear risk	Insufficient information in conference abstract to assess. It states on the trial website that research nurses "are to sit with their back to the women"; however, it is highly probable the nurses would have known the group allocations.

Blinding of outcome assessment	Unclear risk	Insufficient information provided in the in the conference abstract and trial registration document/protocol to confidently assess as ‘high risk’ or ‘low risk’.
Incomplete outcome data	Unclear risk	Outcomes reported in narrative only in the conference abstract reporting the results for this trial.
Selective outcome reporting	Unclear risk	With the conference abstract reporting the results only, unable to assess confidently as ‘high risk’ or ‘low risk’ of bias.
Other Bias	Unclear risk	Insufficient information to confidently assess.

McLachlan 2016		
Methods	RCT: ACTRN12611000898954; Supporting breastfeeding in local communities (SILC) trial; (cluster randomised by LGA unit, 3 intervention arms)	
Participants	<p>7 039 women from ten Local Government Areas (LGA) were randomised</p> <p>Inclusion criteria: LGAs in Victoria, Australia with a lower rate of any breast feeding at discharge from hospital than the Victorian state average, and more than 450 births per year. Exclusion criteria: LGAs that had breastfeeding initiatives in place similar to the proposed interventions.</p> <p>Setting: ten LGAs with breast feeding initiation rates below the state average and > 450 births / year in Victoria, Australia (intervention implemented from July 2012 to March 2013).</p>	
Intervention	<p>Group 1 – Early proactive maternal and child health nurses (MCHN) home-based breastfeeding support (n = 2819 women, 3 LGAs, 26 clusters (health centres) randomised)</p> <p>Women (at risk of early breastfeeding cessation), received a home visit, once during the 7 days prior to the scheduled MCHN nurse visit (73% visited once and 19% visited twice – reported in results) that is part of usual care for women under the public health care system. The home visit was delivered by the trained nurses (SILC-MCHNs). The SILC-MHNS focused, during the home visit, on normalising breastfeeding by providing education and support, including by providing reassurance to build confidence in breast feeding, providing information and guidance (including relating to breast milk expression), assisting with the development of a breastfeeding plan (if needed), and providing a list of potentially useful websites/numbers.</p> <p>Group 2 - Early proactive MCHN home-based breastfeeding support plus drop-in support centres (n = 3335 women, 3 LGAs, 32 clusters (health centres) randomised)</p> <p>Women in this group received the same SILC-MCHN home visit program plus the opportunity to attend an established local community breastfeeding drop-in centre staffed by SILC-MCHNs. Centres were welcoming places that offered access to drinks, change tables and the chance to meet/ learn from other mothers. The participant women were informed about these centres at either the hospital or birth, through flyers provided by MCHN, and various other channels including posters at postnatal clinics and child care centres, and radio.</p> <p>Group 3: (n = 3449 women, 4 LGAs, 41 clusters (health centres) randomised)</p> <p>Women received standard care.</p>	
Outcomes	<p>Data: <u>secondary outcomes</u>: i) breastfeeding (any) at four months</p> <p>Narrative: none</p>	
Notes	<p>Funding: Department of Education and Early Childhood Development, Victoria, Australia.</p> <p>Declaration of interest: none declared</p> <p>This trial with 3 arms was included in the review analysis as two pair-wise comparisons; group 1 versus group 3 (standard care), and group 2 versus group 3 (standard care).</p>	
ROB	Authors' judgement	Support for judgement
Random sequence Generation	Unclear risk	<p>Quote: "Eligible LGAs were randomly allocated to one of the three trial arms, stratified by the number of births per year (large >2500; medium 1000 to 2500; small <1000)"</p> <p>MacLachlan 2016 Pg. 2</p>

Allocation concealment	Low risk	“Allocation to trial arms took place using opaque envelopes at a state-wide MCH forum”.
Blinding of participants and personnel	High risk	As authors report, not possible
Blinding of outcome Assessment	High risk	Primary and secondary outcomes (any breastmilk at different time points), self-reported by the mothers who received the interventions.
Incomplete outcome data	High risk	Of the 3449 women randomised to the control group, only 2414 (69.9%) were available for the primary outcome assessment (breastfeeding at 4 months). Of the 3335 randomised to the home visit support intervention, only 2281 (68.3%) were available. Of the 2891 women assigned to the home visit plus drop in centre intervention, 2344 (81%) were available.
Selective outcome reporting	Low risk	Small range of outcomes reported (breast feeding at various time points), however, outcome measures specified were reported.
Other Bias	High risk	Intervention infidelity (poor compliance with the planned interventions). Quote: “SILC was a complex community-based randomised controlled trial and there were some unanticipated difficulties with intervention implementation: some women were not assessed for a SILC-MCHN visit and some visits did not occur as planned, soon after hospital discharge. Thus, the interventions were diluted, influencing both the reach and dose of the intervention.”

Mirzaie 2018		
Methods	RCT: Iranian Centre for Clinical Trials registration, IRCT201501073706N24	
Participants	<p>74 women were randomised</p> <p>Inclusion criteria: mothers with premature infants 7 to 54 days, born 28 to 34 weeks gestational age, who had not started direct breastfeeding for their babies, were motivated to breastfeed; who had more than a 30% reduction in the amount of milk when compared with previous milk production (based on mother account), or who were unable to provide adequate breast milk to meet the nutritional needs of their infant. Mothers with singleton or twin infants were eligible.</p> <p>Exclusion criteria: being reluctant to attend hospital regularly during seven days (of study) to receive the intervention, tendency to start using a remedy to increase breast milk production or change dosage of taking drugs (to increase supply) within the seven days of the intervention, having an absolute or relative contraindication for breast feeding, with health problems (including for e.g, foot skin ulcers, mastitis, breast abscesses or unfavorable general condition), metabolic disorders of infant, illiteracy of the mother, and unwilling to participate in the study.</p> <p>Setting: neonatal ward or neonatal intensive care unit of Al-Zahra and Taleghani hospital, in Iran (participants recruited from March 2016 to July 2016).</p>	
Intervention	<p>Group 1: (n=37) Women received foot massage, for 10 minutes on each foot (20 minutes in total), once a daily for 7 days, about one and a half hours after the previous expression. In the first five minutes on each foot, the massage was general, focused on the foot soles. In the second 5 minutes, the reflexology focused on pressing points related to breast milk supply.</p> <p>Group 2: (n=37) Women received foot massage for 10 minutes on each foot (20 minutes in total), once daily for 7 days, about one and half hour after the previous milk expression) for 10 min per each foot (total 20 min). For the first 5 minutes on each foot, the massage was the same as in the intervention group. In the second 5 minutes, it was different, with points understood to be irrelevant to breast milk supply.</p>	
Outcomes	<p>Data: <u>primary</u> i) quantity of milk expressed, ii) maternal satisfaction; <u>secondary</u> i) breastfeeding (exclusive), assessed on the last day of the intervention (day 7 day), infant weight, change over the 7-day intervention period (g), maternal health including depression, anxiety and stress, all assessed using the DASS-21 scale.</p> <p>Narrative: none</p>	
Notes	<p>Funding: Research Deputy of Tabriz University of Medical Sciences.</p> <p>Declarations of interest: none declared.</p> <p>This study was performed by a postgraduate student; protocol for trial registered and ethical approach attained.</p>	
ROB	Authors' judgement	Support for judgement
Random sequence generation	Low risk	Authors report use of a computer-generated sequence to ensure random numbers (randomisation was stratified by centre, infant age and number of infants, restricted with randomly varying blocks of four to six).
Allocation concealment	Low risk	"Allocation concealment were implemented using a central method"

Blinding of participants and personnel	Unclear risk	“In this trial, there was no possibility of complete blinding, but participants and outcome assessors were unaware of the group assignment.”
Blinding of outcome assessment	Unclear risk	Not reported.
Incomplete outcome data	Unclear risk	Quote: “All women allocated to the groups received the first day intervention. Two participants discontinued the intervention from the second day; one from the control group who was suspected to potentially have a deep vein thrombosis in her leg and another one in the intervention group who had no suitable general health status. In addition, in the intervention group, two other participants at the second and third, five at the fifth and sixth days did not carry out the massage due to self-reported fatigue and stress. The outcomes were assessed and analysed for all participants”.
Selective outcome reporting	Low risk	All outcomes prespecified in the study protocol reported.
Other bias	Unclear risk	Whilst the authors state that the groups were comparable at baseline, the data comparing the characteristics raise a concern (though small) about potential confounding due to differential consumption of drugs to assist lactation in the two groups (proportion in intervention and control groups 75.5% and 78.4% respectively). This may or may not have influenced the results of the study.

Mohammadpour 2018		
Methods	RCT: Trial registration IRCT2016120126153N3	
Participants	<p>56 women were randomised</p> <p>Inclusion criteria: mother undergoing cesarean section, having given to birth to an infant of 29 to 36 at gestational weeks and admitted to the NICU, resident in the lactating mothers' room, without injury, wound, or tumor on the feet, passage of 3 days since delivery, lack of lactation 3 hours before measuring, and no history of back massage or reflexology use.</p> <p>Exclusion criteria: reluctance to continue the research at any time during the study, having a recent stressful experience (in the past 6 months) including death, divorce, illness or hospitalization, required to take medications affecting breast milk (e.g. antibiotics, anticonvulsants, antipsychotics).</p> <p>Setting: NICUs of Alzahra and Shahid Beheshti hospitals, Isfahan, Iran (study conducted August 2015 to November 2015).</p>	
Intervention	<p>Group 1: (n = 28) Reflexology intervention was performed on the feet of mothers, consisting of one session a day for 6 days. 60 minutes following the reflexology, mothers were asked to collect milk themselves using an electric breast pump.</p> <p>Group 2: (n = 28) Standard care: "Only routine interventions were performed in the control group and the mothers' milk was measured and recorded using the electric breast pump available in the ward every day at 11 a.m. for 6 days."</p> <p>All participants: mothers collected milk themselves using a breast pump for 15 minutes at 11am and measured the milk using a baby milk bottle; measurements were recorded in a table</p>	
Outcomes	<p>Data: <u>primary</u> quantity of milk expressed</p> <p>Narrative: none</p>	
Notes	<p>Funding: Isfahan University of Medical Sciences.</p> <p>Declaration of interest: none declared.</p>	
ROB	Authors' judgement	Support for judgement
Random sequence generation	Unclear risk	"The participants were divided into two groups of intervention and control using convenience sampling and random allocation (lottery method) based on the inclusion criteria...The number of patients was calculated with 95% confidence interval, and 84% test power coefficient as 25 individuals per group. Then, 25 cards with each group name were provided and kept in a bag. Then, each mother of a premature infant selected one of the cares and was placed in the selected group"
Allocation concealment	Unclear risk	How allocation concealed during randomization not reported.

Blinding of participants and personnel	High risk	Participants: not possible to blind due to the nature of the intervention. Personnel: researcher performed reflexology/intervention with participants.
Blinding of outcome assessment	Unclear risk	Not reported.
Incomplete outcome data	Low risk	56 women were randomised, 28 to each group. In both groups 3 women were excluded before the study completion due to death of infants or discharge of infants or lack of interest in continuing. The attrition rate was therefore low and similar in the two groups, as were the reasons for losses.
Selective outcome Reporting	Unclear risk	Not possible to assess confidently as 'high risk' or 'low risk' without access to study protocol (trial registration listed in publication reporting the study, however not accessible).
Other bias	Unclear risk	Whilst authors claim similarity of groups on key characteristics, no data for this comparison is provided.

Niela-Vilen 2016		
Methods	RCT	
Participants	<p>124 women were randomised</p> <p>Inclusion criteria: mothers who delivered infants born <35 weeks gestational age</p> <p>Exclusion criteria: not Finnish speaking.</p> <p>Setting: a neonatal intensive care unit (name not reported) in Finland (study conducted from 2011 to 2015).</p>	
Intervention	<p>Group 1: (n = 60)</p> <p>Mothers in the intervention group were invited to participate in a closed breastfeeding peer-support group delivered via social media (Facebook), based on their individual needs, with no obligation to visit the group at any point. Some mothers joined at discharge (internet not available in hospital), others joined later (after their infant's discharge). Peer support via the social medial platform was provided by three voluntary mothers who had previous experience with breastfeeding a preterm infant. Participating mothers also provided peer support to each other. A midwife was available to answer questions about breastfeeding. Expressing breast milk was mentioned as a top in Facebook posts, including how to maintain supply via expression, and how to use breast pumps.</p> <p>Group 2 (n = 64)</p> <p>Standard care</p>	
Outcomes	<p>Data: none</p> <p>Narrative: <u>secondary feeding</u> i) duration of expressing milk (months), assessed at 12 months postpartum; breastfeeding duration (months), exclusive and any, assessed at 12 months postpartum.</p>	
Notes	<p><u>Funding:</u> authors reported that no funding was received: "This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors".</p> <p><u>Declaration of interest:</u> none declared.</p>	
ROB	Authors' judgement	Support for judgement
Random sequence generation	Low risk	"The randomisation was performed with random permuted blocks."
Allocation concealment	Low risk	"..... mothers were given sealed envelopes including their randomization."
Blinding of participants and personnel	High risk	Blinding of participants and study personnel was not feasible due to the nature of the intervention.
Blinding of outcome assessment	High risk	Structured questionnaires and interviews (at 12 months only) were used to collect data, with reporting by participants and the study personnel.
Incomplete outcome data	High risk	Differences across outcomes in the total number of participants for which results are reported; for key outcomes, including exclusive breast feeding, and duration of expressing milk, close to 50% attrition, in intervention and control groups. For example: for

		duration of exclusive breast-feeding data available for 32/60 and 37/64 women randomised to intervention and control group respectively; for duration of overall breastfeeding, data available for 47/60 and 48/64 women randomised to intervention and control group respectively; for duration of expressing breastmilk, data available for 31/60 and 30/64 women randomised to intervention and control groups respectively.
Selective outcome reporting	High risk	<p>1) No means and SD reported for key outcomes (including breastfeeding duration and exclusive breastfeeding). Medians and inter-quartile ranges reported only. Authors report that they reported this way due to the data not being normally distributed.</p> <p>2) Lack of clarity about time-points of outcomes reported. Some outcomes not reported by group e.g. IIFAS score and Breastfeeding Self-Efficacy – Short Form BSES-SF).</p> <p>3) No published protocol available to compare the reported outcomes against pre-specified outcomes.</p>
Other bias	Low risk	Participants in the two groups similar at baseline. No signs of other bias (all concerns accounted for assessments of other domains).

Parker 2017		
Methods	RCT: NCT01892085	
Participants	184 lactating mothers of extremely preterm infants were randomized. Inclusion criteria: “mothers of VLBW” infants (no further details in conference abstract reporting this study). Exclusion criteria: not reported Setting: USA	
Intervention	Group 1: breast expression within 60 minutes (1 hour) after delivery; n = 60 women Group 2: breast expression within 60 to 179 minutes (1 to 3 hours) after delivery Group 3: breast expression within 180 to 360 minutes (3 to 6 hours) after delivery	
Outcomes	Data: none Narrative: <u>secondary</u> breastfeeding: lactating at 3- and 6-weeks following delivery, and at discharge; ii) maternal physiological effect of expressing or pumping, time to lactogenesis stage II	
Notes	Funding: Not reported Declaration of interest: Not reported Reported in a conference abstract only; authors refer to measurement of the outcome breastmilk volume (“breastmilk volume measured daily for the first 7 days and weekly for the first 6 weeks”) in the methods section of the abstract; however, this is not reported.	
ROB	Authors’ judgement	Support for judgement
Random sequence generation	Unclear risk.	Insufficient information provided in conference abstract to confidently assess as high or low risk.
Allocation concealment	Unclear risk.	Insufficient information.
Blinding of participants and personnel	Unclear risk.	Insufficient information.
Blinding of outcome assessment	Unclear risk.	Insufficient information.
Incomplete outcome data	Unclear risk.	Insufficient information.
Selective outcome reporting	High risk.	Missing data in reporting of results: “mothers who initiated BM expression 1-3 hours following delivery had an earlier onset of lactogenesis stage II (p=0.013)”; breastmilk volume reported as an outcome, however, no results reported. come. Limited range of outcomes reported.
Other bias	Unclear risk.	Insufficient information on methods to confidently assess as “high risk” or “low risk” of other bias.

Steurer 2017

Methods	RCT	
Participants	<p>47 mothers were randomised.</p> <p>Inclusion criteria: mother of premature infant who intended to breastfeed, infant born between 23 – 34 weeks gestational age, with an infant admitted to a neonatal intensive care unit. Gestational age selection was based on criteria for pump dependency for two weeks prior to initiation of milk feeding at the breast.</p> <p>Exclusion criteria: (a) non-English speaking; (b) critically ill; (c) history of breast augmentative surgery. Participants who were critically ill were defined as those unable to perform manual expression or electric pump expression due to illness, weakness, or sedation as determined by the primary physician providing care to the mother. Participants who had undergone breast augmentation surgery were excluded due potential for surgical techniques for both reduction and enhancement to cut or obstruct the milk ducts and thereby preventing mothers from producing milk. Participants nursing at the breast (who did not need to exclusively express milk via artificial methods) were excluded.</p> <p>Setting: USA</p>	
Intervention	<p>Group 1 (n = 16) Women received education, individually on how to express, by hand, and using the electric pump. The education included instruction on the Stamford Technique method of expressing milk by hand. The education was provided by the investigator of the study and video. Women were requested to express by hand before using the electric pump for 7 days (inclusive) after delivery.</p> <p>Group 2 (n = 18) Women received the same breast milk expression education as women in the intervention group. However, they were asked to perform hand expression prior to using the electric pump for 3 days (inclusive) after delivery.</p>	
Outcomes	<p>Data: <u>primary</u> i) quantity of milk expressed; maternal satisfaction (self-efficacy) BSES-SF scale</p> <p>Narrative: none</p>	
Notes	<p>Funding: St Louis Children's Hospital Foundation: Internal Research Grant</p> <p>Declaration of interest: None declared</p>	
ROB	Authors' judgement	Support for judgement
Random sequence generation	Low risk	"Randomization blocks of four were generated by a computerized random number generator to ensure equal allocation of groups." Pg.30 and 33
Allocation concealment	Low risk	"Each study number had a separate sealed envelope containing information on allocation". Pg. 33
Blinding of participants and personnel	High risk	As the author reported, blinding of participants and personnel not feasible due to nature of the intervention assessed. Concern as self-reported outcomes.
Blinding of outcome assessment	High risk	Assessed by participants and lead investigator who were not blind to group assignment.

Incomplete outcome data	Unclear risk	A total of 22 mothers were randomised to the 7 days manual expression group, of which 6 did not complete study; a total of 25 mothers were randomised to the 3-day manual expression group, of which 7 did not complete. Therefore, relatively high attrition (20%), however similar across the two groups.
Selective outcome reporting	Low risk	Comprehensive reporting of study outcomes specified in protocol. However, note that this study assessed a very limited number of outcomes, and did not assess important outcomes, e.g. breastfeeding rates at discharge.
Other bias	Unclear risk	Analysis of baseline characteristics of two groups shows groups similar at baseline. The authors note that a limitation was study recruitment at two different units in the hospital. However, study location did not differ between the groups. Small sample size / limited power to detect an intervention effect: authors aimed to randomize 90 participants, 47 randomised and only 34 assessed and included in review analysis.

Zhang 2017	
Methods	RCT (3 arms)
Participants	<p>164 women were randomised</p> <p>Inclusion criteria: mothers between the ages of 20 and 35 years, with a single-birth primipara, who gave birth by caesarean section to healthy full-term infant (Apgar score ≥ 8), with stable vital signs, who were willing to breastfeed baby on breast and stay in hospital for at least 4 days postpartum.</p> <p>Exclusion criteria: receiving other lactation promotion programs, not planning to breastfeed due to physical or mental problems or other conditions (e.g. mammary dysplasia, breast surgery/injury, hypothyroidism, hypopituitarism, polycystic ovarian syndrome, ovarian theca-lutein cyst, gestational diabetes mellitus, diabetes, hypertension, pregnancy-induced hypertension, placenta implantation, amniotic fluid embolism, or postpartum haemorrhage), mother–infant separation immediately after delivery; maternal smoking, and pre-pregnant maternal BMI $>27 \text{ kg/m}^2$.</p> <p>Setting: Affiliated Hospital of Nantong University and Maternal and Children Health Care Service Hospital, China.</p>
Interventions	<p>Group 1 – high pumping pressure group (n = 56) The cycling rate on the provided hospital pump is 60 cycles/ min with a sucking-release-stopping action in each cycle. Breast pumping pressure was regulated upward from 0 mmHg to a target pressure of -150 mmHg (within 3-5 minutes). This was maintained for 15 minutes on each breast. Breast pumping began within 2 hours after caesarean operation and occurred 6 times per day for 30 minutes per occasion. This continued until onset of lactation. Standard hospital electric breast pumps (CoreMed HLX-1, FutureMed Medical Devices Co., Ltd., Shanghai, China) were used by mothers to express.</p> <p>Group 2 – low pumping pressure group (n = 55) The cycling rate on the provided hospital pump is 60 cycles/ min with a sucking-release-stopping action in each cycle. Breast pumping pressure was regulated upward from 0 mmHg to a target pressure of -100 mmHg (within 3-5 minutes) and maintained for 15 minutes on each breast. Breast pumping began within 2 hours after caesarean operation and occurred 6 times for 30 minutes per occasion. This continued until onset of lactation. Standard hospital electric breast pumps (CoreMed HLX-1, FutureMed Medical Devices Co., Ltd., Shanghai, China) were used by mothers to express.</p> <p>Group 3 - no pressure group (n = 50) No breast pump was given to the mothers in the “control group” before onset of lactation. All participants: received the same assistance, including positioning, latch-on, and breast-feeding technique. The study protocol gave priority to infant feeding; all infants were breastfed on demand and breast fed at breast directly.</p>
Outcomes	<p>Data: <u>primary</u> i) quantity of milk expressed: 8-hour daytime output on day four following onset of lactation; ii) maternal satisfaction (confidence in lactation): H&H Lactation Scale score, assessed at discharge and one month after delivery; <u>secondary</u> feeding i) breastfeeding (exclusive), at discharge, and one month after birth; (g); <i>mother health</i> i) depression: EPDS (score), assessed one month after birth; <i>adverse effects for mother or infant</i> i) mother cracked nipples (yes/no); ii) mother nipple pain, assessed using the visual analogue scale (score)</p> <p>Narrative: none</p>

Notes	<p>Funding: Funding of Nursing Scientific Research of Fudan University, Grant/Award Number FNF201422; Funding of Science and Technology Program of Nantong City, Grant/Award Number: MS12016004; College Students' Innovation Project of Jiangsu Province, Grant/Award Number: 201610304120H.</p> <p>Declaration of interest: none declared.</p> <p>We included group 1 and 2 in the review analysis only, as they are the relevant groups for this review.</p>	
ROB	Authors' judgement	Support for judgement
Random sequence generation	Low risk	Computer-generated random numbers table used.
Allocation concealment	Low Risk	"Group numbers were sealed into the non-transparent envelopes kept by assigned personnel. The grouping was concealed to participant, clinical staff, and research nurses until the entry of study."
Blinding of participants and personnel	High Risk	"Because of the nature of intervention, the masking could no longer be applied after allocation." Pg. 2
Blinding of outcome assessment	Unclear risk	Investigators were blinded to assessing maternal visual analogue & maternal fatigue; however, assessors were not blinded for assessment of other outcomes.
Incomplete outcome data	Unclear risk	50/56 of the mothers randomised to the high-pressure group, and 48/55 participants randomised to the low-pressure group were available for assessment.
Selective outcome reporting	Unclear risk	Without access to the protocol it is not possible to confidently assess selective outcome reporting as high or low risk. Trial registration reported in the Zhang paper, (ChiCTR-IOR-14005321), however not accessible.
Other bias	High risk	Target power calculation final study numbers were not met; 4 participants in each of the pressure groups did not follow the study protocol.

Appendix 5: Citations excluded at full text review with reasons

Citation	Reason for exclusion
1. Adhisivam, B; Vishnu, BB; Poorna, R; Mahalakshmy, T; Pournami, F; Rojo, J, 2017, 'Postnatal counseling on exclusive breastfeeding using video - experience from a tertiary care teaching hospital, south India', <i>Journal of maternal-fetal & neonatal medicine</i> , vol. 30, no. 5: pp. 834-838.	Design: not an RCT
2. Ahmadi, S; Farideh, K; Masoumi, SZ; Parsa, P; Roshanaei, G, 2016, 'Intervention based on BASNEF model increases exclusive breastfeeding in preterm infants in Iran: a randomized controlled trial,' <i>Int Breastfeed J</i> , vol. 11, no. 30: pp. 30.	Intervention: not breastmilk expression intervention
3. Ara, G et al. 2017, 'Does peer counseling promote appropriate infant feeding and better growth in infants in urban slums in Bangladesh?' <i>Annals of nutrition and metabolism</i> . Conference: 21st international congress of nutrition, ICN 2017. Argentina, vol. 71: pp. 97-398 DOI: 10.1159/000480486.	Intervention: not breastmilk expression
4. Ara, G; Khanam, M; Papri, N; Nahar, B; Haque, A; Kabir, L & Dibley, M, 2018, 'Peer counselling improves breastfeeding practices: a cluster randomized controlled trial in urban Bangladesh', <i>Maternal & child nutrition</i> , vol. 14, no. 3: pg. 144 -154, DOI: 10.1111/mcn.12605.	Intervention: not breastmilk expression
5. Araban, M; Karimian, Z; Karimiam, Kakolaki, Z; McQueen, KA; Dennis, CL, 2018, 'Randomized Controlled Trial of a Prenatal Breastfeeding Self-Efficacy Intervention in Primiparous Women in Iran,' <i>JOGNN - Journal of Obstetric, Gynecologic, and Neonatal Nursing</i> , vol. 47, no. 2: pp. 173-183.	Intervention: education about breastfeeding provided, no specific advice relating to breast milk expression.
6. Azza, H; Ahmed, AM; Roumani, SK; Zhang, L and King, D, 2016, 'The Effect of Interactive Web-Based Monitoring on Breastfeeding Exclusivity, Intensity, and Duration in Healthy, Term Infants After Hospital Discharge,' <i>Journal of obstetric, gynecologic, and neonatal nursing: JOGNN</i> , vol. 45, no. 2: pp.143-154 DOI: 10.1016/j.jogn.2015.12.001.	Intervention: education about breastfeeding provided, no specific advice relating to breast milk expression.

7. Balaguer Martinez, JV; Valcarce, P; Esquivel Ojeda, JN; Hernandez Gil, A; Martin Jimenez, MDP; Bernad Albareda, ADP, 2018, 'Telephone support for breastfeeding by primary care: a randomised multicentre trial,' <i>Anales de pediatria</i> (barcelona, spain: 2003), vol. 89, no. 6: pp.1-8 DOI: 10.1016/j.anpedi.2018.02.007.	Not in English; also intervention not breastmilk expression.
8. Cangöl, E. and Sahin, NH, 2017, 'The Effect of a Breastfeeding Motivation Program Maintained during Pregnancy on Supporting Breastfeeding: A Randomized Controlled Trial,' <i>Breastfeeding medicine</i> , vol. 12, no. 4: pp. 218-226.	Intervention: not breast milk expression.
9. Cornell, E, Lener, T, Hagadom, JI, Chapman DJ, Lussier, M, Brownell, E, 2016, 'A well-baby peer counseling program is not associated with human milk receipt in the NICU,' <i>Journal of perinatology</i> Vol. 36, n.9: pp.758-762.	Study design: not RCT.
10. da Silva, CF; Nunes, LM; Schwartz, R; Giugliani, ERJ, 2016, 'Effect of a pro-breastfeeding intervention on the maintenance of breastfeeding for 2 years or more: Randomized clinical trial with adolescent mothers and grandmothers,' <i>BMC pregnancy and childbirth</i> , vol. 16, no 97: pp. 1-6.	Intervention: not breastmilk expression.
11. Ericson, J; Eriksson, M; Hellsteom-Westas, L; Hoddinott, P; Flacking, R, 2018, 'Proactive telephone support provided to breastfeeding mothers of preterm infants after discharge: a randomised controlled trial,' <i>Acta paediatrica, international journal of paediatrics</i> , vol.1, no.5: pp. 791-798.	Intervention: not breast milk expression.
12. Fewtrell, M. Kennedy, K. Aluwalia, J.S. Nicholl, R. Lucas, A. Burton, P. (2016) "Predictors of expressed milk volume in mothers expressing milk for their preterm infant", <i>Archives of Disease in Childhood: Child, Fetal, Neonatal Ed</i> , 101: F502-F506. DOI10.1136/archdischild-2015-308321.	<p>Secondary paper reporting a trial included in Becker 2016 review; no additional data report for inclusion in this update.</p> <p>As in Cochrane Systematic Reviews, these papers are placed with the primary ones.</p>
13. Fontana, C; Menis, C; Pesenti, N; Passera, S; Liotto, N; Mosca, F; Roggero, P; Fumagalli, M, 2018, 'Effects of early intervention on feeding behavior in preterm infants: A randomized controlled trial,' <i>Early human development</i> , vol. 121: pp. 15-20.	Population – infants not mothers received intervention.

14. Gu, Y; Zhu, Y; Zhang, Z; Wan, H, 2016, 'Effectiveness of a theory-based breastfeeding promotion intervention on exclusive breastfeeding in China: a randomised controlled trial,' <i>Midwifery</i> , vol. 42: pp. 93-99 DOI: 10.1016/j.midw.2016.09.010	Duplicate.
15. Harari, N; Rosenthal, MS; Bozzi, V; Goeschel, L; Jayewickreme, T; Onyebeke, C; Griswold, M; Perez-Escamilla, R, 2018, 'Feasibility and acceptability of a text message intervention used as an adjunct tool by WIC breastfeeding peer counsellors: The LATCH pilot,' <i>Maternal and Child Nutrition</i> , vol.14, no.1: pp.1-6.	Breast milk expression intervention not assessed and reported separately.
16. Heon, M, Goulet, C, Garofalo, C, Nuyt, AM, Levy, E 2016, 'An Intervention to Promote Breast Milk Production in Mothers of Preterm Infants', <i>Western Journal of Nursing Research</i> , vol. 38, no.5, pp. 529-552.	Secondary paper reporting a trial included in Becker 2016 review; no additional data report for inclusion in this update. As in Cochrane Systematic Reviews, these papers are placed with the primary ones.
17. Hmone, MP, 2017, 'Impact of SMS text messages to improve exclusive breastfeeding and reduce other adverse infant feeding practices in Yangon, Myanmar: a randomized controlled trial,' <i>Annals of nutrition and metabolism. Conference: 21st international congress of nutrition</i> , ICN 2017. Argentina, vol.71, 610-611 DOI: 10.1159/00048048.	Intervention – not breastmilk expression.
18. Jayaraman, D; Mukhopadhyay, K; Bhalla, AK; Dhaliwal, LK, 2017, 'Randomized Controlled Trial on Effect of Intermittent Early Versus Late Kangaroo Mother Care on Human Milk Feeding in Low-Birth-Weight Neonates', <i>Journal of human lactation</i> , vol. 33, no. 3: pp. 533-539 DOI: 10.1177/0890334416685072.	Intervention: kangaroo care not breastmilk expression assessed.
19. Karbandi, S; Hosseini, SM; Hosseini, SA; Sadeghi, F; Hesari, M & Masoudi, R, 2017, 'Evaluating the Effectiveness of Using a Progressive Muscle Relaxation Technique on the Self-Efficacy of Breastfeeding in Mothers With Preterm Infants' <i>Journal of nursing research</i> , vol. 25: pp.283-288 DOI: 10.1097/JNR.0000000000000217.	Intervention. An RCT investigating the effect of muscle relaxation techniques on the self-efficacy of breastfeeding mothers. Expressing was not listed as an intervention nor was any expressing recorded in the outcomes.

<p>20. Kim, TH; Lee, HH; Kim, JM; Kimn, Y, 2016, 'Re: professional breastfeeding support for first-time mothers: a multi-centre cluster randomised controlled trial', <i>Bjog</i>, vol. 123: pp. 2052 DOI: 10.1111/1471-0528.14121.</p>	<p>Design – education and support for breastfeeding, intervention may have included a component on breastmilk expression, but not support for breastmilk expression not the focus of the intervention.</p>
<p>21. Kimani-Murage, EW et al, 2017, 'Effectiveness of the baby friendly community initiative on exclusive breastfeeding in rural Kenya,' <i>Annals of nutrition and metabolism. Conference: 21st international congress of nutrition</i>, ICN 2017. Argentina, vol. 71, pp. 590-591 DOI: 10.1159/000480486.</p>	<p>Outcome. Conference paper so information limited. "The intervention involved regular counselling and support of mothers by trained community health volunteers and health professionals on maternal, infant and young child nutrition". Pg. 590 - Breast milk expression not specifically mentioned. No - Breast milk expression outcomes listed.</p>
<p>22. Kittithanesuan, Y & Kaewkungwal, J, 2017, 'Effect of music on immediately postpartum lactation by term mothers after giving birth: A randomized controlled trial,' <i>Journal of the Medical Association of Thailand</i>, vol. 100, no.8: pp. 834-842.</p>	<p>Outcome. This trial included mothers of babies who were suckling at the breast.</p>
<p>23. Kuppuswamy, V; Logan S; Sridhar, J; O'Brien, E; Ranganathan, D; Manthirum, K; Narayan, A; Summer, A, 2016, 'Effect of a home-based intervention by trained community health nurses on immunization rates, exclusive breastfeeding, growth parameters, and hospitalizations for respiratory and diarrheal illness-a pilot randomized controlled trial' <i>Annals of global health. Conference: 7th annual CUGH conference: bridging to a sustainable future in global health</i>. United states. Conference start: 20160409. Conference end: 20160411, vol. 82, no.3:pp.323- 323.</p>	<p>Outcome Conference paper so information limited. Home based counselling includes counselling around breastfeeding among other issues. This may or may not include - Breast milk expression. Breast milk expression not specifically stated. No breast milk expression outcomes mentioned.</p>
<p>24. Laliberte, C; Dunn, S; Pound, C; Sourial, N; Yasseen, AS; Millar, D; White, RR; Walker, M & Lacaze-Masmonteil, T, 2016, 'A Randomized Controlled Trial of Innovative Postpartum Care Model for Mother-Baby Dyads,' <i>PloS one</i>, vol. 11, no. 2: pp. e0148520.</p>	<p>Intervention listed as "breastfeeding assessment and support". Level of support such as the teaching of breast milk expression is not specified.</p>
<p>25. Liu, L; Zhu, J; Jinqiu, Y; Wu, M; Ye, Benlan, 2017, 'The Effect of a Perinatal Breastfeeding Support Program on Breastfeeding Outcomes in Primiparous Mothers.' <i>Western journal of nursing research</i>, vol. 39, no.7: pp. 906-923.</p>	<p>Design – not RCT.</p>

<p>26. López-Dicastillo, (2017) Synergy, Self-efficacy, Breastfeeding and Care (Sinergia, Autoeficacia, Lactanciay Cuidados), viewed 31st July, 2018, https://clinicaltrials.gov/show/nct03019484</p>	<p>Non-randomised intervention: written information & watch a breastfeeding self-efficacy video, specific advice with active listening after watching a breastfeed, follow-up phone call to address any issues. Intervention may have included - Breast milk expression as part of breastfeeding management - Breast milk expression not specifically stated.</p>
<p>27. Manahan, K; Kerver, J; Olson, B; Rozga, M, 2016, 'Topic and Timing of Breastfeeding Education is Associated with Reasons for Breastfeeding Discontinuation,' <i>Journal of the Academy of Nutrition & Dietetics</i>, vol. 116, no. 9: pp. A34-A34.</p>	<p>Design. "Prenatally enrolled participants were followed prospectively...". Pg. A-34 Conference paper so information limited.</p>
<p>28. Martinez-Brockman, JL; Harani, N; Segura-Perez, S; Goeschel, L; Bozzi, V; Escamilla, R, 2018, 'Impact of the Lactation Advice Through Texting Can Help (LATCH) Trial on Time to First Contact and Exclusive Breastfeeding among WIC Participants,' <i>J Nutr Educ Behav</i>, vol. 50, no. 1: pp. 33-42.e31.</p>	<p>Not a breast milk expression intervention.</p>
<p>29. Martin-Iglesias, S; Santamaria-Martin, MJ ; Alonso-Alvarez, A; Rico-Blazquez, M; Del Cura-Gonzalez, I; Rodriguez-Barrientosn, R; Barbera-Martin, A; Sanz-Cuesta, T; Isabel Coghen-Vigueras, M. ; de Antonio-Ramirez, I; Durand-Rincon, I; Garrido-Rodriguez, F; Geijo-Rincon, MJ; Mielgo-Salvador, R; Morales-Montalva, MS; Reviriego-Gutinrrez, MA; Rivero-Garrido, C; Ruiz-Calabria, M; Santamaria-Mechano, MP; Santiago-Fernandez, R; Sillero-Quintana, MI; Soto-Almendo, B; Terol-Claramonte, M; Villa-Arranz, M, 2018, 'Effectiveness of an educational group intervention in primary healthcare for continued exclusive breast-feeding: PROLACT study,' <i>BMC pregnancy and childbirth</i>, vol. 18, no. DOI: 10.1186/s12884-018-1679-3</p>	<p>Breast milk expression intervention as part of breastfeeding education, with no separate analysis for breastmilk expression.</p>
<p>30. Maslowsky, J; Frost, S; Hendrick, CE; Trujilo Cruz, FO; Merajver, S, 2016, 'Effects of postpartum mobile phone-based education on maternal and infant health in Ecuador,' <i>International journal of gynaecology and obstetrics</i>, vol.134, no.1; pp.93-98 DOI: 10.1016/j.ijgo.2015.12.008</p>	<p>Design – prospective evaluation study, not an RCT.</p>

31. Masoumi, SZ; Kazemi, F; Ahadi, S, 2017, 'Investigating the effects of instructing mothers using BASNEF model on continuing exclusive breastfeeding of late- preterm infants,' <i>Journal of comprehensive pediatrics</i> , vol. 8, no. 2: pp. 1-9.	Breast expression not tested as an intervention.
32. Meek, JY and Noble, L, 2016, 'Implementation of the ten steps to successful breastfeeding saves lives,' <i>JAMA pediatrics</i> , vol. 170, no. 10: pp. 925-926.	Design – commentary on a guideline implementation process.
33. Mikami, FCF; De Lourdes Brizot, M; Tase, TH; Saccuman, E; Vieira Francisco, RP, Zugaib, M, 2017, 'Effect of Prenatal Counseling on Breastfeeding Rates in Mothers of Twins,' <i>JOGNN: Journal of Obstetric, Gynecologic & Neonatal Nursing</i> , vol. 46, no. 2: pp. 229-237.	The intervention evaluated in this RCT (delivered in the antenatal and immediate postnatal period), did not include any guidance or other methods of support relating to breastmilk expression. See Brizot NCT
34. NCT02724969. Mobile, Semi-automated Text Message-based Intervention to Prevent Perceived Low or Insufficient Milk Supply. https://clinicaltrials.gov/show/nct02724969 . (first received March 31 st 2016).	No breast milk expression intervention.
35. NCT02738957. Effect of Prenatal Counseling on Breastfeeding Rates in Twins. https://clinicaltrials.gov/show/nct02738957 (first received April 14 th 2016).	Intervention: not breast milk intervention.
36. NCT03030651. Effect of Breastfeeding Education and Support Intervention on Timely Initiation and Exclusive Breastfeeding. https://clinicaltrials.gov/show/nct03030651 (first received January 25 th 2017).	Breast milk expression not assessed separately
37. NCT03247491. Effectiveness of a Mindfulness and Compassion Intervention for Pregnant Women and Their Partners for the Prevention of Stress and Depression During Pregnancy and Breastfeeding. https://clinicaltrials.gov/show/nct03247491 (first received August 11th 2017).	Intervention: education about breastfeeding provided, no specific advice relating to breast milk expression.
38. NCT03332108, Novel Approach to Improving Lactation Support With Mobile Health Technology. https://clinicaltrials.gov/show/nct03332108 (first received November 2017)	Intervention: breastmilk expression not identified as intervention component.

39. NCT03357549. Project to Promote Breastfeeding. https://clinicaltrials.gov/show/nct03357549 (first received November 30 th 2017)	Intervention: not breastmilk expression
40. NCT03442517. The LATCHING Pilot Project. https://clinicaltrials.gov/ct2/show/NCT03442517 (first received February 22 2018)	Intervention: education about breastfeeding provided, no specific advice relating to breast milk expression.
41. NCT03481166. Women Empowered Through Education to Breastfeed. https://clinicaltrials.gov/show/nct03481166 . 42. (first received March 29 th 2019)	Protocol for an RCT assessing breastfeeding promotion.
43. Nikiéma, L; Huybregts, L; Martin-Prevel, Y; Donnen, P; Lanou, H; Grosemans, J; Offoh, P; Dramaix-Wilmet, M; Sondo, B; Roberfroid, D; Kolsteren, P, 2017, 'Effectiveness of facility-based personalized maternal nutrition counseling in improving child growth and morbidity up to 18 months: a cluster-randomized controlled trial in rural Burkina Faso,' <i>PloS one</i> , vol.12, no. 5: pp. e0177839 DOI: 10.1371/journal.pone.0177839	No breast milk expression intervention assessed.
44. Nilsson, IMS; Strandberg-Larsen, K; Knight, CH; Hansen, AV; Kronberg, H, 2017, 'Focused breastfeeding counselling improves short- and long-term success in an early-discharge setting: A cluster-randomized study,' <i>Maternal and Child Nutrition</i> , vol.13, no. 4: pp.1-10.	Intervention: breastfeeding program (mainly around efficacy & breastfeeding), breastmilk expression not specifically mentioned.
45. Omekara, FH, 2018, 'Hand Expression with Lactation Support: Effect on Self-Efficacy and Breastfeeding Duration', Doctoral Dissertation, Walden University, Minneapolis, USA.	Study design - observational study.
46. Palacios, C; Campos, M; Gibby, C; Melendez, M; Lee, JE; Banna, J, 2018, 'Effect of a Multi-Site Trial using Short Message Service (SMS) on Infant Feeding Practices and Weight Gain in Low-Income Minorities,' <i>Journal of the American College of Nutrition</i> , vol. 37, no.7: pp.1-9 DOI:10.1080/07315724.2018.1454353	Intervention: breast milk expression not specifically mentioned.

<p>47. Peres, KG; Nascimento, GG; Peres, MA; Mittinty, MN; Demarco, FF; Santos, IS; Matijasevich, A; Barros, Aluisio, JD, 2017, 'Impact of Prolonged Breastfeeding on Dental Caries: A Population-Based Birth Cohort Study,' <i>Pediatrics</i>, vol. 140, no.1: pp. 1-7.</p>	<p>Design: observational study assessing effects on dental caries of prolonged breastfeeding.</p>
<p>48. Reimers, P; 2018, 'A Cluster Randomised Trial to Determine the Efficacy of the "Feeding Buddies" Program in Improving Exclusive Breastfeeding Rates Among HIV-Infected Women in Rural KwaZulu-Natal, South Africa,' <i>AIDS Behav</i>, vol. 22, no.1: pp. 212-223.</p>	<p>Intervention: breast milk expression may have been taught re "safe complementary feeding but not specifically mentioned in interventions or outcome.</p>
<p>49. Singh, V; Ahmed,S; Dreyfuss, ML; Kiran, U; Chaudhery, DN; Srivastava, VK; Ahuja, RC; Baqui, AH; Darmstadt, GL; Santosham, M; West, KP, 2017, 'An integrated nutrition and health program package on IYCN improves breastfeeding but not complementary feeding and nutritional status in rural northern India: a quasi-experimental randomized longitudinal study,' <i>PloS one</i>, vol. 12, no. 9. e0185030 DOI: 10.1371/journal.pone.0185030</p>	<p>Intervention: breast milk expression not specifically reported.</p>
<p>50. Stuebe, AM; Bonuck, K; Adatorwovor, R Schwartz, TA; Berry, DC, 2016, 'A Cluster Randomized Trial of Tailored Breastfeeding Support for Women with Gestational Diabetes,' <i>Breastfeeding medicine</i>, vol. 11, no.1: pp.504-513 DOI: 10.1089/bfm.2016.0069</p>	<p>Intervention: not breastmilk expression.</p>
<p>51. Stuebe, AM; Bonuck, K; Adatorwovor, R; Schwartz, TA; Berry, D, 2016, 'A tailored breastfeeding support intervention for women with gestational diabetes,' <i>American journal of obstetrics and gynecology</i>, vol 214, no. 1: pp. S68.</p>	<p>Intervention: not breastmilk expression.</p>
<p>52. Tully, KP; Holditch, D; White-traut, RC; David, R; O'Shea, TM; Geraldo, V, 2016, 'A Test of Kangaroo Care on Preterm Infant Breastfeeding,' <i>Journal of obstetric, gynecologic, and neonatal nursing: JOGNN</i>, vol. 45, no. 1: pp.45-61 DOI: 10.1016/j.jogn.2015.10.004</p>	<p>Intervention: not breastmilk expression.</p>

53. Unger, J; Ronen, K; Perrier, T; Derenzi, B; Slyker, J; Drake, AI; Mogaka, D; Kinuthia, J; John-Stewart, G, 2018, 'SMS communication improves exclusive breastfeeding and early postpartum contraception in a low to middle income country setting: A randomised trial,' <i>Bjog</i> , vol. 125, no.12 : pp. 1620-1629.	Intervention: not breast milk expression.
54. Uscher-Pines, 2017, Expanding Rural Access to Breastfeeding Support Via Telehealth: the Tele-MILC Trial, viewed 31st July 2018, https://clinicaltrials.gov/show/nct02870413	Intervention: not breastmilk expression (education on breastfeeding antenatally & activity sheets & postnatal questionnaire, does not specifically report on breast milk expression support).
55. Wood, NK; Woods, NF; Blackburn, ST; Sanders, EA, 2016, 'Interventions that enhance breastfeeding initiation, duration, and exclusivity,' <i>MCN The American Journal of Maternal/Child Nursing</i> , vol.41, no. 5: pp. 299-307.	Study design: review.
56. Yanhong, GU; 2016, 'Effectiveness of a theory-based breastfeeding promotion intervention on exclusive breastfeeding in China: A randomised controlled trial, <i>Midwifery</i> , 42: 93-99.	Intervention: not breastmilk expression.
57. Zunza, M; Cotton, MF; Mguagbaw, L; Lester, R; Thabane, L, 2017, 'Interactive weekly mobile phone text messaging plus motivational interviewing in promotion of breastfeeding among women living with HIV in South Africa: study protocol for a randomized controlled trial,' <i>Trials</i> , vol. 18, no.1, pp.331. DOI: 10.1186/s13063-017-2079-0	Intervention: not breastmilk expression

Appendix 6: Ongoing and awaiting classification studies

	Studies ongoing	Support for judgement
1.	Hagi-Pedersen, MB; Norlyk, A; Dessau, R; Stanchev, H; Kronborg, H, 2017, 'Multicentre randomised study of the effect and experience of an early in home programme (PreHomeCare) for preterm infants using video consultation and smartphone applications compared with in-hospital consultations: protocol of the PreHomeCare study', BMJ open 7, vol. 7, no. 3. DOI: 10.1136/bmjopen-2016-013024	Study protocol
2.	NCT03247491. PUMP (Providing the Underprivileged with Manual Pump): an RCT. https://clinicaltrials.gov/ct2/show/NCT03192241 (first received 20 th June 2017)	Study protocol

	Articles awaiting classification	Support for judgement
1.	NCT02756169. Maternal Obesity and Breastfeeding Performance. https://clinicaltrials.gov/show/nct02756169 (first received April 29th 2016)	Trial complete. Awaiting publication.
2.	NCT02989766. A Self-Guided Breastfeeding Program. https://clinicaltrials.gov/show/nct02989766 (first received December 12 2016)	Awaiting publication.

Appendix 7: Breastmilk expression guidance adapted from Healy 2016 study

Expressing Breastmilk for your Baby

Important Facts

Your breastmilk protects your baby.

Hold your baby *skin to skin* when your baby is ready to be held with the help of a nurse or midwife.

The more breastmilk you express in the first 2 weeks, the more breastmilk you will make later.

Handwashing

Before handling breastmilk, wash your hands and nails with liquid soap and running water (for at least 15 seconds) and dry them with a clean or disposable towel.

Alcohol rubs can be used in the hospital setting to clean hands if they are not visibly dirty.



Expressing Your Breastmilk

There are two ways to express your breastmilk which are hand expressing and pumping. Your midwife will show you how to do both.

The First 24 hours:

Ask your midwife to teach you how to hand express drops of colostrum (first breastmilk) from your breast into a sterile container or sterile syringe.

Ask your midwife to show you how to use an electric breast pump (*hospital grade*), either on the ward or in the Neonatal Unit (NNU).

Pumping and hand expressing together makes more milk.

Try to pump in the first 6 hours and at least 6 times in the first 24 hours. You may only get a few drops of breastmilk. This is a good start.

Day 2:

Pump every 2 to 3 hours for 10-15 minutes per breast (minimum 8-10 times in 24 hours) e.g. 8am, 11am, 2pm... Avoid a gap of more than 5 to 6 hours overnight.

Pumping both breasts at the same time i.e. double pumping saves time.

Use the highest comfortable pump setting. There may be slight discomfort, but pumping should not be painful.

Tell your midwife when you have milk so that it can be given to your baby.

Day 3 & Day 4:

Pump every 2 to 3 hours for 10-15 minutes per breast (minimum 8-10 times in 24 hours) e.g. 8am, 11am, 2pm... etc. and at least once at night. Avoid a gap of more than 5 to 6 hours overnight.

When your milk comes in your breasts will feel full. Pumping more often will help you feel more comfortable.

Drinking a glass of water before you sleep at night will wake you naturally and this will be a good time to pump.

In the Days to Follow and During the 1st Month:

Pump every 3 hours for 10-15 minutes per breast (**minimum 8 times in 24 hours**) and at least once at night. Avoid a gap of more than 5 to 6 hours overnight.

Aim for a milk supply of **600-900 mls** per day by the time your baby is 10 days old. Keeping a diary of the number of times you pump and how much milk you make can be useful.

Some mothers may not reach this amount but continue to pump as often as you can as every drop helps your baby.

After the 1st Month or so:

Once your milk supply is established, you should continue to express **6 to 8 times per day, every 3 to 4 hours** and at least once at night to maintain your milk supply.

When your baby is ready to breastfeed, you should try to put your baby to the breast after you have expressed that breast (empty breast).

Hold your baby *skin to skin* when your baby is ready to be held. Your skin should touch your baby's skin.

Hand Expression

This is useful for expressing small amounts of colostrum (first milk) from the breast while your baby is in the NNU. Begin expressing your colostrum within 6 hours of birth. Ask your nurse or midwife for help while you learn to hand express.

Step 1. Wash your hands. Make yourself comfortable and begin by massaging your breast using gentle movements

Step 2. Hold a small sterilised container near the breast

Step 3. Place your thumb and first finger opposite each other on the edge of the areola (Darkened area around the breast)



Step 4. Keep your fingers in place and gently press your thumb and finger backwards towards your chest wall as you press and release the breast tissue

Step 5. At first a few drops will only appear but continue pressing and releasing as in a 'rolling action' and your milk will start to appear. Rotate your fingers around the areola to release milk from all areas of the breast



Step 6. After a few minutes of expressing the flow will stop. Change to the other breast and continue to hand express.

Pumping in the hospital:

In the hospital use a sterile funnel valve and membrane (in a sealed pack) (see Figures A and B) at each pumping session.

The breast shield of the funnel is a medium size but is available in other sizes if required. The breast shield of the funnel should be placed with the nipple in the centre. Light pressure is required to obtain a patent seal, firm pressure will inhibit milk flow as the ducts are easily compressed.

Mothers should not set the suction level on the breast pump too high as this will cause friction and make nipples sore. They should note the suction level that suits them best.

Wipe the funnel clean after use with a disposable paper towel

The pump should be switched off before trying to remove the collection funnel.

Wipe the external surface of the pump and tubing thoroughly after every pumping session, with clinical detergent wipes which are available in the parenting rooms on the wards or in the expressing room in the NNU.

For mothers who are in patients these hospital grade pumps are available for use in the postnatal wards and the NNU. When mothers are discharged from the hospital these pumps may be loaned to mothers from the NNU or are also available to rent.



Figure B.



Pumping at home:

It is recommended to use a hospital grade electric breast pump at home.

Wash the funnel, valve and membrane with washing-up liquid and water and then sterilise.

There are three ways to sterilise the equipment at home.

1. Steam

This is the best method and you can use an electric steam steriliser or a microwave version. Use sterile tongs to remove equipment from the machine.



2. Boiling Water

If boiling use a large saucepan with a tight fitting lid. The water should cover all the pumping equipment being sterilised. The water should be brought to the boil and kept boiling for at least **3 minutes**. Keep the saucepan covered until you need to use the equipment.



3. Chemical Steriliser

Make up a batch of sterilising liquid (e.g. Milton) and follow instructions. All equipment should be completely covered by liquid with no trapped air bubbles. The equipment should be covered for the time stated on the instructions.



Containers

During the first few days after a baby is born mothers produce small amounts of colostrum. This can be collected directly into a small (1-5ml) sterile single-use syringe in amounts for single feeds. This milk can then be used directly from the syringe or stored in a sterile polypropylene container (Beldico container).

Single use (disposable) sterile plastic polypropylene containers should be used. In CUMH the containers used are Beldico containers which are available in sizes 60 and 120 mls. These sterile containers are sealed and are pre wrapped in sterile plastic wrapping.

Plastic bags, stainless steel containers and household plastic containers are not suitable as they are difficult to handle, they can leak and fat from the milk can adhere to the plastic and be lost from the milk.

After a mother has pumped a space of at least 1-2 cm approximately should be left at the top of the container so that if the milk is frozen it can expand without breaking the container.

The caps of the container should be securely tightened.

Labels

Label each container of breast milk with an adhesive printed hospital baby label

Record on the label the date and time of collection

Ensure you have a supply of containers and baby labels to use these are available in either the wards or the NNU

Transporting Breastmilk to the hospital from home:

Bring freshly pumped milk to the hospital each day in a cooler bag with ice packs to keep the milk cool (ice packs are cooler than ice)

Freeze extra milk at home or in the freezer in the neo natal unit expressing room

The nurse or midwife will give you sterile containers to store the milk in.

Label each bottle using the printed baby labels and write the date and time on each bottle.

Refrigerate milk after pumping, freeze milk that will not be used within 48 hours.

Storing Breastmilk in the hospital and at home:

	For Use in the Neonatal Unit	For Use at Home
Room Temperature (25°C)	4 hours	6 hours
Refrigerator (2°C to 4°C)	48 hours	5 days
Icebox of fridge (-4°C)	2 weeks	2 weeks
Separate Freezer section of Fridge Freezer (-18°C to -20°C)	3 months	3 months
Deep Freezer (-18°C to -20°C)		6 months

Using defrosted Breastmilk in the hospital and at home:

Milk defrosted by:	For Use in the Neonatal Unit	For Use at Home
Standing in a fridge (2-4°C)	Once removed from fridge use within 4 hours If kept in fridge, use within 24 hours from the start of defrosting	Once removed from fridge use within 4 hours If kept in fridge, use within 24 hours (after it has defrosted)

Warming in water	Use immediately	Use immediately
Standing at Room Temperature (25°C)	Not recommended	Use immediately or place in fridge and use within 12hrs

Suggestions how to maintain supply of breastmilk:

Hold baby in skin to skin

Hold your baby skin-to-skin as soon as possible after delivery and continue to do so as frequently as possible – depending on how well your baby is. If the baby is not ready to breastfeed, it may still be possible to offer your baby your breast to suckle, i.e. the baby does not receive milk but the suckling action stimulates milk production.

Focus on baby

Try to express near your baby. If you are away from your baby it can help to think of your baby while expressing milk, using as many senses as possible (e.g. touch, smell, sight and sound) as visual and sensory stimulation help promote the flow of milk. Suggestions for you to do while expressing include:

Imagine the baby lying against you

Visualise your baby's face and hands

Think of your baby's name

Hold one of your baby's blankets, or a piece of their clothing, or a toy (that smells of your baby)

Visit the baby or call the unit to see how your baby is doing before pumping

Look at a photograph of your baby

Relax

Try to relax as much as possible when expressing milk. The following suggestions may help:

Express in a calm and private environment

Listen to relaxing music

Imagine running water

Sit comfortably with your back straight and well supported

Back massage – it may be helpful to have someone massage your back before expressing, as this can help stimulate milk flow.

Slow breathing – this can help you to relax.

Take time

Give yourself plenty of time to express milk and allow extra time for preparation/organisation before and afterwards.

Rest, eat to appetite and drink to thirst

Try to get adequate rest and sleep, eat regularly (to match appetite) and drink fluids frequently (to match thirst). Some mothers find they need to drink and/or eat while expressing.

Practice breast massage

Practice gentle breast massage before starting to express in order to stimulate milk ejection. Examples of massage techniques include

Gently massage the breast with the fingertips

Gently stroke the breast with gentle feather-like movements

Gently stroke the nipple with the palm of the hand

Gently stroke the area under the nipple and areola with flat hands in an upward movement

Gently roll a closed fist over the breast towards the nipple

Gently roll the nipple between the thumb and forefinger

Massage should feel comfortable – if it is painful you should stop and ask for advice. If the flow of milk reduces while you are expressing it may be helpful to massage your breasts again to encourage milk flow and then re-start expressing. Breast massage in conjunction with double pumping has been shown to improve both milk output and fat content.

Try breast compression (deep tissue massage)

Breast compression while pumping can stimulate the milk ejection reflex, helping milk to flow more quickly. Gently squeeze your breast using your thumb on one side of the breast and your finger on the other side (fairly far back from the nipple). Do not roll your fingers along your breast, nor squeeze so hard that it hurts or changes the shape of the nipple area (areola). When the milk stops flowing release the squeeze, wait a short time, and then begin again.

Apply warmth

Applying warmth to the breast (e.g. warm flannel, wash cloth or a heat pad; or taking a warm bath or shower) prior to expressing can help the milk flow.

Follow a routine

It may help to develop a routine to encourage milk flow, e.g. massage breasts, have a warm bath or shower, or apply warm flannels to the breast prior to expressing. Even just following the same routine when preparing to express milk can help stimulate milk flow.

Double pump

Use a double pump and double pump set if you need to express frequently or long-term (e.g. for a preterm or unwell baby) or to stimulate your breast milk supply.

Alternate breasts if single pumping

If a mother is single pumping (e.g. if hand pumping colostrum) it sometimes helps to switch from breast to breast during the expressing session; or to massage/stimulate one breast/nipple while pumping the other breast. Remember that single pumping may not be as effective as double pumping for frequent or long-term use.

Use appropriate breast shields

Use milk breast shields (opening of the funnel) in a size that feels comfortable.

Support breasts

Support your breasts from underneath while expressing. Place your fingers flat on your ribs with your index finger placed where the breast meets the ribs, this helps to support the breast tissue forward into the funnel of the breast shield.

Include breaks

It may be helpful to take one-minute breaks during an expression session and to massage both breasts during these breaks.

Empty breasts

Continue to express until your breasts are 'emptied' of milk, i.e. after each expressing session breasts should feel well drained and thoroughly softened. There is no exact time limit. It may help to continue to express for approximately 2 minutes after the milk flow has stopped or has slowed to an occasional drip. 'Emptying' breasts helps stimulate milk production for the next expressing session. Also, the milk towards the end of an expressing session (hindmilk) is richer in fat and calories, which is important for a baby's growth.

Wear an appropriate bra

Wear a comfortable bra that supports your breasts. Nursing bras are available with openings in the cup that allow easier access. It may be helpful to wear a bra that has been adapted to hold double collection sets securely, allowing you to pump hands free. Mothers report that such a bra helps them feel more relaxed and leads to increased milk volume. Under-wired bras should not be worn as they can damage tender breast tissue and may cause blocked milk ducts.

Avoid oestrogen containing hormonal contraception

Avoid oestrogen containing hormonal contraception (e.g. the combined pill) during the early post-natal period as this can affect your supply of breast milk. Oestrogen may reduce milk supply and the duration of breastfeeding. Alternatives may be required that do not affect breast milk (e.g. progesterone only pill or non-hormonal contraception)

Avoid alcohol and smoking

Alcohol and nicotine can pass to babies through breast milk. Therefore, alcohol and smoking should be avoided, especially in the time immediately before expressing.

Smoking may also slow down the flow of milk and make it more difficult to express. Nicotine prevents milk let down. If you are unable to avoid smoking try to reduce the number of cigarettes smoked and to avoid smoking before expressing or a breastfeed.

Alcohol may also decrease the milk ejection reflex and produce changes in babies' sleep patterns resulting in less sleep overall. In addition, moderate to heavy alcohol consumption by the nursing mother may inhibit milk intake, affect infant motor development, slow weight gain and cause other side effects in the baby.

A table for mothers to record quantity of milk expressed was also included in this protocol.

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